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 see 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.

INDICATION[1]

RYBREVANT *FASPRO* (amivantamab and hyaluronidase-lpuj) is indicated as a single agent for the treatment of adult patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) whose disease has progressed on or after platinum-based chemotherapy and an anti-PD-(L)1 antibody.

- Limitations of use: RYBREVANT *FASPRO* is not indicated as a treatment for patients with oropharyngeal squamous cell carcinoma (OPSCC) that is human papillomavirus (HPV)-associated (i.e., by p16 IHC).
- 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 a confirmatory trial(s).

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.

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

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.

In OrigAMI-4 (n=132), all Grade ARRs occurred in 16% of patients. All reactions were Grade 1 or 2. Of the patients who experienced ARRs, 91% 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 ARR during injection in a setting where cardiopulmonary resuscitation medication and equipment are available. For the first dose, monitor patients for hypersensitivity and ARRs for 2 to 4 hours following the end of injection. Interrupt injection if ARR is suspected. Resume treatment upon resolution of symptoms or permanently discontinue based on severity.

CPT®, Current Procedural Terminology; FDA, U.S. Food and Drug Administration; HCPCS, Healthcare Common Procedure Coding System.

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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 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 Support Program Patient Authorization Form

2 **Submit a PA or medical exception request**

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



Prior Authorization Checklist



Exceptions Request Checklist



Sample Letter of Medical Necessity and Appeal Template

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



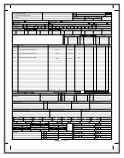
Where to Order

4 **Submit a reimbursement claim for RYBREVANT *FASPRO* and the administration 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 to 8:00 PM ET. Care Navigators do not provide medical advice.

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Coding Summary for RYBREVANT *FASPRO*

Information	Code type	Code and descriptor	Outpatient hospital	Physician office
Diagnosis	ICD-10-CM	**C00.3** Malignant neoplasm of upper lip, inner aspect **C00.4** Malignant neoplasm of lower lip, inner aspect **C00.5** Malignant neoplasm of lip, unspecified, inner aspect **C00.6** Malignant neoplasm of commissure of lip, unspecified **C00.8** Malignant neoplasm of overlapping sites of lip **C00.9** Malignant neoplasm of lip, unspecified **C01** Malignant neoplasm of base of tongue **C02.0** Malignant neoplasm of dorsal surface of tongue **C02.1** Malignant neoplasm of border of tongue **C02.2** Malignant neoplasm of ventral surface of tongue **C02.3** Malignant neoplasm of anterior two-thirds of tongue, part unspecified **C02.4** Malignant neoplasm of lingual tonsil **C02.8** Malignant neoplasm of overlapping sites of tongue **C02.9** Malignant neoplasm of tongue, unspecified **C03.0** Malignant neoplasm of upper gum **C03.1** Malignant neoplasm of lower gum **C03.9** Malignant neoplasm of gum, unspecified **C04.0** Malignant neoplasm of anterior floor of mouth **C04.1** Malignant neoplasm of lateral floor of mouth **C04.8** Malignant neoplasm of overlapping sites of floor of mouth **C04.9** Malignant neoplasm of floor of mouth, unspecified **C05.0** Malignant neoplasm of hard palate **C05.1** Malignant neoplasm of soft palate **C05.2** Malignant neoplasm of uvula **C05.8** Malignant neoplasm of overlapping sites of palate **C05.9** Malignant neoplasm of palate, unspecified **C06.0** Malignant neoplasm of cheek mucosa **C06.1** Malignant neoplasm of vestibule of mouth **C06.2** Malignant neoplasm of retromolar area **C06.80** Malignant neoplasm of overlapping sites of unspecified parts of mouth **C06.89** Malignant neoplasm of overlapping sites of other parts of mouth **C06.9** Malignant neoplasm of mouth, unspecified **C09.0** Malignant neoplasm of tonsillar fossa **C09.1** Malignant neoplasm of tonsillar pillar (anterior) (posterior) **C09.8** Malignant neoplasm of overlapping sites of tonsil **C09.9** Malignant neoplasm of tonsil, unspecified **C10.0** Malignant neoplasm of vallecula **C10.1** Malignant neoplasm of anterior surface of epiglottis **C10.2** Malignant neoplasm of lateral wall of oropharynx **C10.3** Malignant neoplasm of posterior wall of oropharynx	✓	✓

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

Coding Summary for RYBREVANT *FASPRO* (cont'd)

Information	Code type	Code and descriptor	Outpatient hospital	Physician office
Diagnosis	ICD-10-CM	**C10.4** Malignant neoplasm of branchial cleft **C10.8** Malignant neoplasm of overlapping sites of oropharynx **C10.9** Malignant neoplasm of oropharynx, unspecified **C12** Malignant neoplasm of pyriform sinus **C13.0** Malignant neoplasm of postcricoid region **C13.1** Malignant neoplasm of aryepiglottic fold, hypopharyngeal aspect **C13.2** Malignant neoplasm of posterior wall of hypopharynx **C13.8** Malignant neoplasm of overlapping sites of hypopharynx **C13.9** Malignant neoplasm of hypopharynx, unspecified **C14.0** Malignant neoplasm of pharynx, unspecified **C14.8** Malignant neoplasm of overlapping sites of lip, oral cavity, and pharynx **C32.0** Malignant neoplasm of glottis **C32.1** Malignant neoplasm of supraglottis **C32.2** Malignant neoplasm of subglottis **C32.3** Malignant neoplasm of laryngeal cartilage **C32.8** Malignant neoplasm of overlapping sites of larynx **C32.9** Malignant neoplasm of larynx, unspecified **Z92.21** Personal history of antineoplastic chemotherapy	✓	✓
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	✓	✓

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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Dosage and Administration

Select Important Dosage and Administration Information 8

Recommended Premedications 8

Every-4-Week Dosing—RYBREVANT *FASPRO* 9

Every-3-Week Dosing—RYBREVANT *FASPRO* 10

Concomitant and Prophylactic Medications 11

Preparation and Administration 11

SELECT IMPORTANT SAFETY INFORMATION (cont'd)

Interstitial Lung Disease/Pneumonitis

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

In OrigAMI-4, ILD/pneumonitis occurred in 1.5% of patients, including one fatal case (0.8%). All of these patients permanently discontinued RYBREVANT *FASPRO* due to ILD/pneumonitis.

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

Dermatologic Adverse Reactions

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

In OrigAMI-4, rash occurred in 81% of patients, including Grade 3 in 11% and Grade 4 in 0.8%. Rash led to a dose reduction in 11% of patients, and permanent discontinuation in 3% of patients.

When initiating treatment, 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.

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. Withhold, reduce the dose, or permanently discontinue RYBREVANT *FASPRO* based on severity.

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Select Important Dosage and Administration Information[1]

- **RYBREVANT *FASPRO* is for subcutaneous use only.** Do not administer RYBREVANT *FASPRO* intravenously
- RYBREVANT *FASPRO* must be administered by a healthcare professional
- RYBREVANT *FASPRO* is not indicated for use in pediatric patients
- Discard unused portion

Contraindications[1]

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

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*[1]

The recommended dosages, dose volume, and vial selection of RYBREVANT *FASPRO* based on baseline body weight, are provided below.

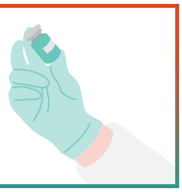
Every-4-Week Dosing

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§‖

Please see the Prescribing Information for RYBREVANT *FASPRO* for units of hyaluronidase for each dose.

*Dose adjustments not required for subsequent body weight changes.

†Following weekly doses from Weeks 1 to 4.

‡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.

Q4W, every 4 weeks.

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Every-3-Week Dosing—RYBREVANT *FASPRO*[1]

The recommended dosages of RYBREVANT *FASPRO* based on baseline body weight are provided below. Administer RYBREVANT *FASPRO* until disease progression or unacceptable toxicity.

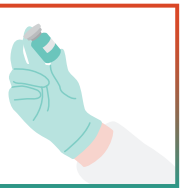
Every-3-Week Dosing

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

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.
†Following weekly doses from Week 1 to 3.
‡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 unit hyaluronidase/22-mL vial will not be needed. Discard unused portion.

Q3W, every 3 weeks.

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Concomitant and Prophylactic Medications[1]

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.

Preparation and Administration[1]

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

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.

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Coding

ICD-10-CM Diagnosis Coding 13

HCPCS Codes 15

National Drug Codes 16

CPT® Codes 18

Other Coding Considerations 19

Physician Office Sample Claim Form (CMS-1500)
for RYBREVANT *FASPRO* (1,600 mg amivantamab and 20,000 units hyaluronidase) 24

Hospital Outpatient Department Sample Claim Form (CMS-1450)
for RYBREVANT *FASPRO* (2,240 mg amivantamab and 28,000 units hyaluronidase) 25

SELECT IMPORTANT SAFETY INFORMATION (cont'd)

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.

In OrigAMI-4, ocular toxicity occurred in 11% of patients, including 0.8% Grade 4. Keratitis occurred in one patient (0.8%).

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

Embryo-Fetal Toxicity

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

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.

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

Code	Description[3]
C00.3	Malignant neoplasm of upper lip, inner aspect
C00.4	Malignant neoplasm of lower lip, inner aspect
C00.5	Malignant neoplasm of lip, unspecified, inner aspect
C00.6	Malignant neoplasm of commissure of lip, unspecified
C00.8	Malignant neoplasm of overlapping sites of lip
C00.9	Malignant neoplasm of lip, unspecified
C01	Malignant neoplasm of base of tongue
C02.0	Malignant neoplasm of dorsal surface of tongue
C02.1	Malignant neoplasm of border of tongue
C02.2	Malignant neoplasm of ventral surface of tongue
C02.3	Malignant neoplasm of anterior two-thirds of tongue, part unspecified
C02.4	Malignant neoplasm of lingual tonsil
C02.8	Malignant neoplasm of overlapping sites of tongue
C02.9	Malignant neoplasm of tongue, unspecified
C03.0	Malignant neoplasm of upper gum
C03.1	Malignant neoplasm of lower gum
C03.9	Malignant neoplasm of gum, unspecified
C04.0	Malignant neoplasm of anterior floor of mouth
C04.1	Malignant neoplasm of lateral floor of mouth
C04.8	Malignant neoplasm of overlapping sites of floor of mouth

Code	Description[3]
C04.9	Malignant neoplasm of floor of mouth, unspecified
C05.0	Malignant neoplasm of hard palate
C05.1	Malignant neoplasm of soft palate
C05.2	Malignant neoplasm of uvula
C05.8	Malignant neoplasm of overlapping sites of palate
C05.9	Malignant neoplasm of palate, unspecified
C06.0	Malignant neoplasm of cheek mucosa
C06.1	Malignant neoplasm of vestibule of mouth
C06.2	Malignant neoplasm of retromolar area
C06.80	Malignant neoplasm of overlapping sites of unspecified parts of mouth
C06.89	Malignant neoplasm of overlapping sites of other parts of mouth
C06.9	Malignant neoplasm of mouth, unspecified
C09.0	Malignant neoplasm of tonsillar fossa
C09.1	Malignant neoplasm of tonsillar pillar (anterior) (posterior)
C09.8	Malignant neoplasm of overlapping sites of tonsil
C09.9	Malignant neoplasm of tonsil, unspecified
C10.0	Malignant neoplasm of vallecula
C10.1	Malignant neoplasm of anterior surface of epiglottis
C10.2	Malignant neoplasm of lateral wall of oropharynx

*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.

ICD-10-CM Diagnosis Coding (cont'd)

Code	Description[3]
C10.3	Malignant neoplasm of posterior wall of oropharynx
C10.4	Malignant neoplasm of branchial cleft
C10.8	Malignant neoplasm of overlapping sites of oropharynx
C10.9	Malignant neoplasm of oropharynx, unspecified
C12	Malignant neoplasm of pyriform sinus
C13.0	Malignant neoplasm of postcricoid region
C13.1	Malignant neoplasm of aryepiglottic fold, hypopharyngeal aspect
C13.2	Malignant neoplasm of posterior wall of hypopharynx
C13.8	Malignant neoplasm of overlapping sites of hypopharynx
C13.9	Malignant neoplasm of hypopharynx, unspecified
C14.0	Malignant neoplasm of pharynx, unspecified
C14.8	Malignant neoplasm of overlapping sites of lip, oral cavity, and pharynx

Code	Description[3]
C32.0	Malignant neoplasm of glottis
C32.1	Malignant neoplasm of supraglottis
C32.2	Malignant neoplasm of subglottis
C32.3	Malignant neoplasm of laryngeal cartilage
C32.8	Malignant neoplasm of overlapping sites of larynx
C32.9	Malignant neoplasm of larynx, unspecified
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.

HCPCS Code

HCPCS Code[4]

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)[5] and claims for many private payers.[6] 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.[7]

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[5,8]:

- 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 see 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.[9] 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.[8,10]

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.[11] 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.[11]

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[11]	Description[11]
96401	Chemotherapy administration, subcutaneous or intramuscular; nonhormonal antineoplastic

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[12]:

- **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[11]
- **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[11]
- The administration of medications (eg, antiemetics, steroidal agents) administered independently or sequentially as supportive management of chemotherapy administration should be separately reported[11]

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[11]

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[11]

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.[11] 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[11]	• Patient requires distinct E/M service in addition to drug administration procedure[11] • Must be substantiated with documentation[11] • Append the modifier to the relevant E/M code[11]	✓ Required by Medicare	✓ Required by Medicare
PO*	Excepted service provided at an off-campus, outpatient, PBD of a hospital[13]	• 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[13]	• 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[15]	• 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[15]	• 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 see 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 see 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[17]:

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]

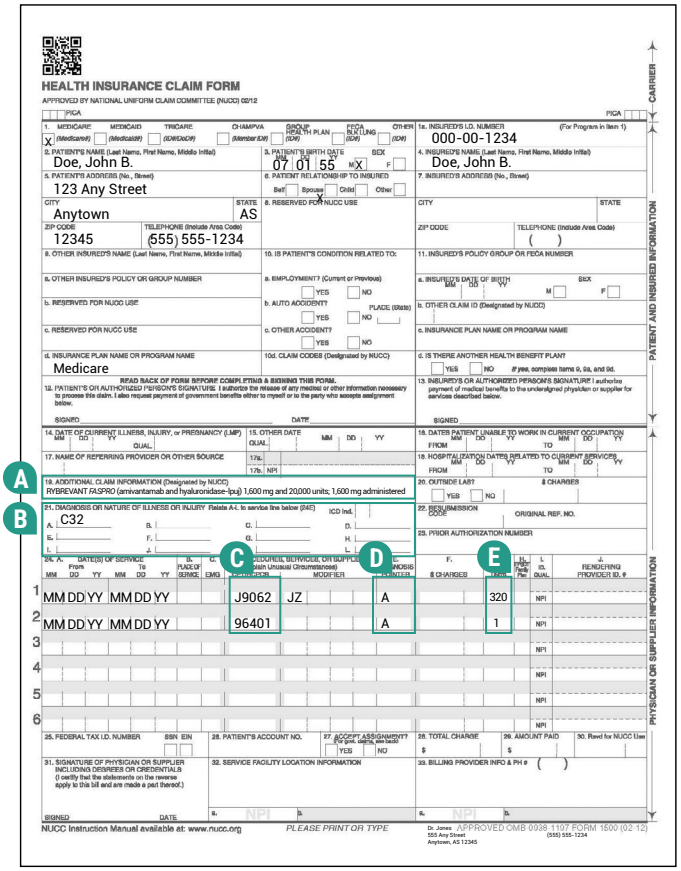
Drugs Supplied at No Cost to Patient

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.[18] 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 | MEDICAID | TRICARE | CHAMPVA | GROUP HEALTH PLAN | FECA BLK LUNG | OTHER
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 | Spouse | Child | Other
7. INSURED'S ADDRESS
CITY: Anytown | STATE: AS
8. RESERVED FOR NUCC USE
ZIP CODE: 12345 | TELEPHONE: (555) 555-1234
9. OTHER INSURED'S NAME
10. IS PATIENT'S CONDITION RELATED TO:
11. INSURED'S POLICY GROUP OR FECA NUMBER
9a. OTHER INSURED'S POLICY OR GROUP NUMBER
10a. EMPLOYMENT? (Current or Previous) YES NO
11a. INSURED'S DATE OF BIRTH | SEX
9b. RESERVED FOR NUCC USE
10b. AUTO ACCIDENT? YES NO PLACE (State)
11b. OTHER CLAIM ID (Designated by NUCC)
9c. RESERVED FOR NUCC USE
10c. OTHER ACCIDENT? YES NO
11c. INSURANCE PLAN NAME OR PROGRAM NAME
9d. INSURANCE PLAN NAME OR PROGRAM NAME: Medicare
10d. CLAIM CODES (Designated by NUCC)
11d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE
13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP)
15. OTHER DATE
16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE
17a.
17b. NPI
18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC): RYBREVANT FASPRO (amivantamab and hyaluronidase-lpuj) 1,600 mg and 20,000 units; 1,600 mg administered
20. OUTSIDE LAB? YES NO | $ CHARGES
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY: A. C32
22. RESUBMISSION CODE | ORIGINAL REF. NO.
23. PRIOR AUTHORIZATION NUMBER

24A. DATE(S) OF SERVICE From To	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 MM DD YY MM DD YY			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 | 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.)
32. SERVICE FACILITY LOCATION INFORMATION
33. BILLING PROVIDER INFO & PH #
SIGNED | DATE | a. NPI | b.

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® codes, 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.

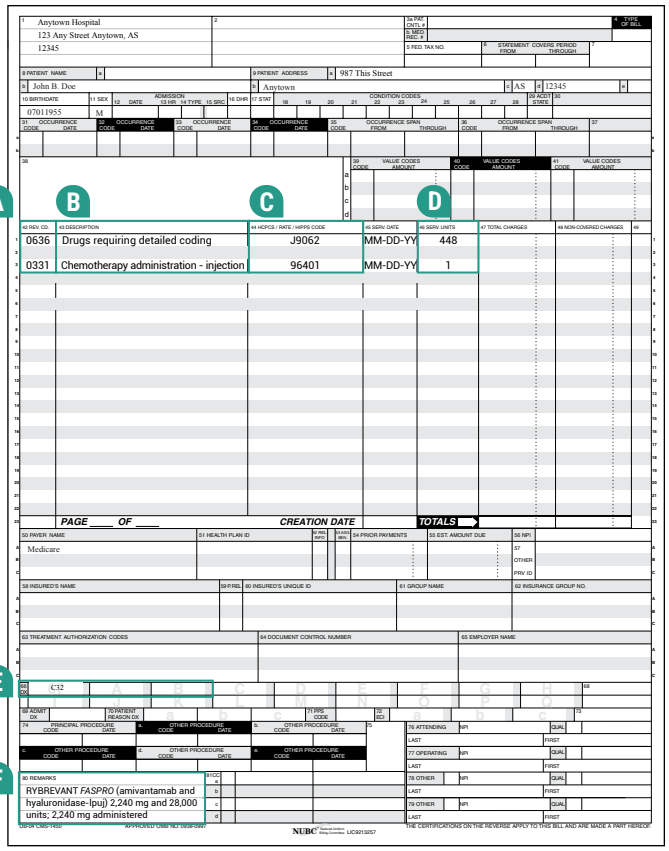
*For doses resulting in discarded amounts, CMS does not use fractional billing units. Therefore, the JW modifier should not be used when the dose of the drug administered is less than the billing unit.[20]

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 see 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; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

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

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

Access and Patient Support

Where to Order..... 27

Coverage Decisions 28

SELECT IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

In OrigAMI-4 (n=102), the most common adverse reactions (≥20%) were rash (79%), fatigue (39%), nail toxicity (35%), stomatitis (32%), and edema (28%). The most common Grade 3 or 4 laboratory abnormalities (≥2%) were decreased lymphocytes (26%), decreased potassium (9%), decreased hemoglobin (6%), increased alanine aminotransferase (4.9%), decreased albumin (4.9%), decreased sodium (4.9%), increased aspartate aminotransferase (3.9%) and decreased white blood cells (2%).

Serious adverse reactions occurred in 39% of patients. Serious adverse reactions in ≥2% of patients included pneumonia (8%), hemorrhage (4.9%), dysphagia (2.9%), pneumothorax (2.9%), anemia (2%), dyspnea (2%), fatigue (2%), hepatic enzyme increased (2%), and ILD/pneumonitis (2%). Fatal adverse reactions occurred in 6% of patients who received RYBREVANT *FASPRO* including sudden death (2%), myocardial ischemia, tumor hemorrhage, aspiration pneumonia, and ILD/pneumonitis (1%, 1 patient each).

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[22]:

- 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* from the authorized specialty distributors listed below.

Specialty Authorized Distribution Network			
Name	**Phone number**	**Fax**	**Website**
BioCare Specialty Distribution	800-304-3064	N/A	biocare-us.com
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
Cardinal Health P.R. 120 (Puerto Rico)	787-625-4200	787-625-4398	cardinalhealth.pr
Cencora (AmerisourceBergen)	800-746-6273	800-547-9413	asdhealthcare.com
Cencora Oncology Supply (AmerisourceBergen Oncology Supply)	800-633-7555	800-248-8205	oncologysupply.com
CuraScript SD (Priority Healthcare)	877-599-7748	800-862-6208	curascriptsd.com
McKesson Plasma and Biologics	877-625-2566	888-752-7626	connect.mckesson.com
McKesson Specialty Health	**Oncology** 800-482-6700 **Multispecialty** 855-477-9800	**Oncology** 855-824-9489 **Multispecialty** 800-800-5673	mckessonspecialtyhealth.com
Morris & Dickson Specialty Distribution	800-388-3833	318-798-6007	morrisdickson.com mdspecialtydist.com

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

Coverage Decisions

Third-party payers may require more than a prescription to cover RYBREVANT *FASPRO*. 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.[23] 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 1 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 HNSCC 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).[24]

Items you may want to prepare when requesting a PA:

- Letter of Medical Necessity
- Prescribing information
- 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.[25]

View a sample HNSCC Letter of Appeal 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 professional. 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.[26]

Tips for Filing an Appeal[26]

- 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 appeal letter, Letter of Medical Necessity, patient records, etc)

PA, prior authorization.

INDICATION

RYBREVANT *FASPRO* (amivantamab and hyaluronidase-lpuj) is indicated as a single agent for the treatment of adult patients with recurrent or metastatic HNSCC whose disease has progressed on or after platinum-based chemotherapy and an anti-PD-(L)1 antibody.

- Limitations of use: RYBREVANT *FASPRO* is not indicated as a treatment for patients with OPSCC that is HPV-associated (i.e., by p16 IHC).
- 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 a confirmatory trial(s).

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.

In OrigAMI-4 (n=132), all Grade ARRs occurred in 16% of patients. All reactions were Grade 1 or 2. Of the patients who experienced ARRs, 91% 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 ARR during injection in a setting where cardiopulmonary resuscitation medication and equipment are available. For the first dose, monitor patients for hypersensitivity and ARRs for 2 to 4 hours following the end of injection. Interrupt injection if ARR is suspected. Resume treatment upon resolution of symptoms or permanently discontinue based on severity.

Interstitial Lung Disease/Pneumonitis

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

In OrigAMI-4, ILD/pneumonitis occurred in 1.5% of patients, including one fatal case (0.8%). All of these patients permanently discontinued RYBREVANT *FASPRO* due to ILD/pneumonitis.

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

Important Safety Information continues →

Please see full Prescribing Information for RYBREVANT *FASPRO*.

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

IMPORTANT SAFETY INFORMATION (cont'd)

Dermatologic Adverse Reactions

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

In OrigAMI-4, rash occurred in 81% of patients, including Grade 3 in 11% and Grade 4 in 0.8%. Rash led to a dose reduction in 11% of patients, and permanent discontinuation in 3% of patients.

When initiating treatment, 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.

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. Withhold, reduce the dose, or permanently discontinue RYBREVANT *FASPRO* 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.

In OrigAMI-4, ocular toxicity occurred in 11% of patients, including 0.8% Grade 4. Keratitis occurred in one patient (0.8%).

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

Embryo-Fetal Toxicity

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

ADVERSE REACTIONS

In OrigAMI-4 (n=102), the most common adverse reactions (≥20%) were rash (79%), fatigue (39%), nail toxicity (35%), stomatitis (32%), and edema (28%). The most common Grade 3 or 4 laboratory abnormalities (≥2%) were decreased lymphocytes (26%), decreased potassium (9%), decreased hemoglobin (6%), increased alanine aminotransferase (4.9%), decreased albumin (4.9%), decreased sodium (4.9%), increased aspartate aminotransferase (3.9%) and decreased white blood cells (2%).

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cp-606849v1

Please see full Prescribing Information for RYBREVANT *FASPRO*.

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

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

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