



Billing and Coding Guide

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

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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: MEDICAID ☐ TRICARE ☐ CHAMPVA ☐ OTHER ☐ (For Program in Item 1)

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

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

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

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

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

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

8. INSURED'S POLICY OR GROUP NUMBER:

9. INSURED'S DATE OF BIRTH: 07/01/55

10. INSURED'S POLICY OR GROUP NUMBER: 000-00-1234

11. INSURED'S POLICY OR GROUP NUMBER:

12. INSURED'S POLICY OR GROUP NUMBER:

13. INSURED'S POLICY OR GROUP NUMBER:

14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (MM/DD/YY): 07/01/55

15. OTHER DATE (MM/DD/YY):

16. DATE OF BIRTH (MM/DD/YY): 07/01/55

17. NAME OF PROVIDER OR OTHER SOURCE:

18. ADDITIONAL CLAIM INFORMATION (Designated by NUCC):
RYBREVANT FASPRO™ (amivantamab and hyaluronidase-lpui) 1,600 mg and 20,000 units; 1,600 mg administered

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC):
RYBREVANT FASPRO™ (amivantamab and hyaluronidase-lpui) 1,600 mg and 20,000 units; 1,600 mg administered

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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™
J9999 – Not otherwise classified antineoplastic drugs

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™
J9999 – Enter the HCPCS units according to the code descriptor (NOC/miscellaneous drug codes are always reported as a unit of "1")

Injection Services

96401 – Enter 1 unit for each injection (for practitioners, Medicare allows up to 3 units of 96401 per date of service¹)

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

*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. Drug codes classified as NOC/miscellaneous are reported with an HCPCS unit of "1" regardless of dose. In this situation, the billing provider or supplier would not append the JW modifier but would report administering the full billing unit along with the JZ modifier.²

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; MAC, Medicare Administrative Contractor; NOC, not otherwise classified.

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

RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpui)
Subcutaneous injection | 1,600 mg/20,000 units | 2,240 mg/28,000 units

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

Anytown Hospital
123 Any Street Anytown, AS
12345

PATIENT NAME: John B. Doe
PATIENT ADDRESS: 987 This Street
CITY: Anytown, AS 12345

DATE OF SERVICE: 07/01/1955
CPT CODE: 0331
HCPCS CODE: 96401
JZ MODIFIER: 1

DRUG NAME: RYBREVANT FASPRO™ (amivantamab and hyaluronidase-lpuj)
STRENGTH: 2,240 mg and 28,000 units
AMOUNT ADMINISTERED: 2,240 mg amivantamab and 28,000 units

DIAGNOSIS CODE: C34.30

PAGE 1 OF 1
CREATION DATE: 07/01/1955
TOTALS: 1

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™

C9399 – Unclassified drugs or biologics

Modifiers

The JZ modifier does not apply to C9399²

Drug Administration

96401 – Chemotherapy administration, subcutaneous or intramuscular; nonhormonal antineoplastic

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

RYBREVANT FASPRO™

C9399 – Enter the HCPCS units according to the code descriptor (NOC/miscellaneous drug codes are always reported as a unit of “1”)

Injection Services

96401 – Enter 1 unit for each injection

For facilities, Medicare allows up to 4 units of 96401 per date of service³

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 and strength and amount administered

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

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; MAC, Medicare Administrative Contractor; NOC, not otherwise classified.

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RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 1,600 mg/20,000 units | 2,240 mg/28,000 units



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 | 1,600 mg/20,000 units | 2,240 mg/28,000 units



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.



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.

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.

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 ($\geq 20\%$) 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 ($\geq 2\%$) 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%).

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



RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 1,600 mg/20,000 units | 2,240 mg/28,000 units



IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

RYBREVANT FASPRO™ with LAZCLUZE® (cont'd)

Serious adverse reactions occurred in 33% of patients, with those occurring in $\geq 2\%$ 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) ($\geq 20\%$) 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 ($\geq 2\%$) 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 $\geq 2\%$ 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 ($\geq 20\%$) 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 ($\geq 2\%$) were decreased neutrophils (49%), decreased white blood cells (42%), decreased lymphocytes (28%), decreased platelets (17%), decreased hemoglobin (12%), decreased potassium (11%), decreased sodium (11%), increased alanine aminotransferase (3.9%), decreased albumin (3.8%), and increased gamma-glutamyl transferase (3.1%).

In MARIPOSA-2, serious 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 ($\geq 20\%$) 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 ($\geq 2\%$) 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 $\geq 2\%$ 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.

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



RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 1,600 mg/20,000 units | 2,240 mg/28,000 units



IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

Intravenous Amivantamab as a Single Agent

In CHRYSALIS (n=129), the most common ARs ($\geq 20\%$) 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 ($\geq 2\%$) 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 $\geq 2\%$ 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-491010v1

References: 1. Medicare NCCI Medically Unlikely Edits (MUEs). Practitioner Services MUE Table. Effective January 1, 2026. Accessed December 9, 2025. <https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medicare-ncci-medically-unlikely-edits-mues> 2. Medicare Program Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Frequently Asked Questions. Centers for Medicare & Medicaid Services. Accessed December 9, 2025. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf> 3. Medicare NCCI Medically Unlikely Edits (MUEs). Facility Outpatient Hospital Services MUE Table. Effective January 1, 2026. Accessed December 9, 2025. <https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medicare-ncci-medically-unlikely-edits-mues>



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(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 1,600 mg/20,000 units | 2,240 mg/28,000 units