Rybrevant Faspro™ (amivantamab and hyaluronidase-lpuj) (Subcutaneous)

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Dates Reviewed: 02/2026

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 2,240 mg amivantamab and 28,000 units hyaluronidase for 1 dose, then 3,360 mg amivantamab and 42,000 units hyaluronidase every 7 days x 4 doses, and then every 14 days thereafter

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**
- Member has been instructed/counseled on limiting sun exposure and the use of protective clothing and/or broad-spectrum UVA/UVB sunscreen; **AND**

Universal Criteria [1]

- Therapy will not be used concomitantly with intravenous amivantamab; **AND**

Non-Small Cell Lung Cancer (NSCLC) † [1]

- Member has locally advanced or metastatic disease; **AND**
  - Used in combination with lazertinib; **AND**
    - Used as first-line treatment; **AND**
    - Member has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutation positive disease as detected by an FDA-approved or CLIA compliant test❖; **OR**
  - Used in combination with carboplatin and pemetrexed in patients with nonsquamous histology; **AND**
    - Used as first-line therapy; **AND**
      - Member has EGFR exon 20 insertion mutation positive disease as detected by an FDA-approved or CLIA compliant test❖; **OR**

- Used as subsequent therapy; **AND**
  - Member has EGFR exon 19 deletion or exon 21 L858R substitution mutation positive disease as detected by an FDA-approved or CLIA compliant test❖; **AND**
  - Used following disease progression on or after treatment with an EFGR tyrosine kinase inhibitor (i.e., osimertinib); **OR**
- Used as a single agent; **AND**
  - Used as subsequent therapy; **AND**
  - Patient has EGFR exon 20 insertion mutation positive disease as detected by an FDA-approved or CLIA compliant test❖; **AND**
  - Used following disease progression on or after treatment with platinum-based chemotherapy

❖ *If confirmed using an immunotherapy assay – http://www.fda.gov/companiondiagnostics*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Prior authorization validity can be renewed based upon the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread, unless otherwise specified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hypersensitivity and administration-related reactions (ARR), interstitial lung disease, pneumonitis, venous thromboembolic events (e.g., deep vein thrombosis, pulmonary embolism), dermatologic adverse reactions (e.g., dermatitis acneiform, pruritus, dry skin, toxic epidermal necrolysis [TEN]), ocular toxicity (e.g., keratitis, blepharitis, dry eye symptoms, conjunctival redness, blurred vision, visual impairment, ocular itching, eye pruritus, uveitis), etc.

V. Dosage/Administration [1]

<table>
<tr><th>Indication</th><th>Dose</th></tr>
<tr><td>NSCLC</td><td><u>In combination with carboplatin and pemetrexed:</u>
<table>
<tr><th>Body weight at baseline [a]</th><th>Recommended Dose</th><th>Dosing Schedule**</th></tr>
<tr><td rowspan="2">< 80 kg</td><td>1,600 mg amivantamab and 20,000 units hyaluronidase</td><td>First dose at Week 1 Day 1</td></tr>
<tr><td rowspan="2">2,400 mg amivantamab and 30,000 units hyaluronidase</td><td>Weekly (total of 2 doses) from Weeks 2 to 3
• Weeks 2 to 3: Injection on Day 1</td></tr>
<tr><td>Every 3 weeks starting at Week 4 onwards</td></tr>
</table></td></tr>
</table>

≥ 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

NOTE:
- Continue treatment with Rybrevant Faspro until disease progression or unacceptable toxicity.
- Members currently receiving intravenous amivantamab at an every 3-week dosing regimen may switch to subcutaneous Rybrevant Faspro at an every 3-week dosing regimen at their next scheduled dose on or after Week 4.

Single agent or in combination with lazertinib:

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

NOTE:
- Continue treatment with Rybrevant Faspro until disease progression or unacceptable toxicity unless otherwise specified.
- Members currently receiving intravenous amivantamab at an every 2-week dosing regimen may switch to subcutaneous Rybrevant Faspro at an every 2-week dosing regimen at their next scheduled dose on or after Week 5.

[a] Dose adjustments not required for subsequent body weight changes.

***NOTE:** RYBREVANT FASPRO must be administered by a healthcare professional.*

VI. Billing Code/Availability Information

HCPCS Code:

- J9999 – Not otherwise classified, antineoplastic drugs

NDC(s):

- Rybrevant Faspro 1,600 mg amivantamab and 20,000 units hyaluronidase per 10 mL solution in a single-dose vial: 57894-0510-xx
- Rybrevant Faspro 2,240 mg amivantamab and 28,000 units hyaluronidase per 14 mL solution in a single-dose vial: 57894-0514-xx

VII. References

1. Rybrevant Faspro [package insert]. Horsham, PA; Janssen Biotech, Inc.; December 2025. Accessed January 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for amivantamab and hyaluronidase-lpuj. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2026.
3. Park K, Haura EB, Leighl NB, et al. Amivantamab in EGFR Exon 20 Insertion-Mutated Non-Small-Cell Lung Cancer Progressing on Platinum Chemotherapy: Initial Results From the CHRYSALIS Phase I Study. J Clin Oncol. 2021 Oct 20;39(30):3391-3402. doi: 10.1200/JCO.21.00662. Epub 2021 Aug 2. PMID: 34339292; PMCID: PMC8791812.
4. Zhou C, Tang KJ, Cho BC, et al; PAPILLON Investigators. Amivantamab plus Chemotherapy in NSCLC with EGFR Exon 20 Insertions. N Engl J Med. 2023 Nov 30;389(22):2039-2051. doi: 10.1056/NEJMoa2306441. Epub 2023 Oct 21. PMID: 37870976.
5. Cho BC, Felip E, Hayashi H, et al. MARIPOSA: phase 3 study of first-line amivantamab + lazertinib versus osimertinib in EGFR-mutant non-small-cell lung cancer. Future Oncol. 2022 Feb;18(6):639-647. doi: 10.2217/fon-2021-0923. Epub 2021 Dec 16. PMID: 34911336.
6. Passaro A, Wang J, Wang Y, et al; MARIPOSA-2 Investigators. Amivantamab plus chemotherapy with and without lazertinib in EGFR-mutant advanced NSCLC after disease progression on osimertinib: primary results from the phase III MARIPOSA-2 study. Ann Oncol. 2024 Jan;35(1):77-90. doi: 10.1016/j.annonc.2023.10.117. Epub 2023 Oct 23. PMID: 37879444.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
Z85.118	Personal history of other malignant neoplasm of bronchus and lung

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC