Rybrevant® (amivantamab-vmjw)
(Intravenous)

Document Number: IC-0607

Last Review Date: 04/04/2024
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Dates Reviewed: 06/2021, 10/2021, 04/2022, 04/2023, 04/2024

I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Rybrevant 350 mg/7 mL solution as a single-dose vial: 5 vials per 7 days initially for 5 weeks, no dose on week 6, then 12 vials every 42 days thereafter

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

- 875 billable units (1750 mg) every 7 days for 5 weeks, no dose on week 6, then 2100 billable units (4200 mg) every 42 days thereafter

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient 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]

- Patient does not have untreated brain metastases (clinically stable asymptomatic brain metastases are allowed); **AND**

Non-Small Cell Lung Cancer (NSCLC) † ‡ [1-5]

- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used in combination with carboplatin and pemetrexed in patients with nonsquamous histology; **AND**
    - Used as first-line therapy; **AND**

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- Patient has epidermal growth factor receptor (EGFR) exon 20 insertion mutation positive disease as detected by an FDA-approved or CLIA compliant test❖; **OR**

▪ Used as subsequent therapy; **AND**

- Patient has EGFR exon 19 deletion or exon 21 L858R or EGFR S768I, L861Q, and/or G719X mutation positive disease as detected by an FDA-approved or CLIA compliant test❖; **AND**
- Used following disease progression on osimertinib for symptomatic systemic disease with multiple lesions; **OR**

o Used as a single agent; **AND**

▪ Used as subsequent therapy; **AND**

▪ Patient has epidermal growth factor receptor (EGFR) exon 20 insertion mutation positive disease as detected by an FDA-approved or CLIA compliant test❖

❖ *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]

Coverage can be renewed based upon the following criteria:

- Patient 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; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, interstitial lung disease, pneumonitis, dermatologic adverse reactions (e.g., acneiform dermatitis, pruritis, dry skin, toxic epidermal necrolysis [TEN]), ocular toxicity (e.g., keratitis, dry eye symptoms, conjunctival redness, blurred vision, visual impairment, ocular itching, 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>< 80 kg</td><td>1400 mg</td><td>Weekly (total of 4 doses) from Weeks 1 to 4
• Week 1: split infusion on Day 1 and Day 2
• Weeks 2 to 4: infusion on Day 1
• Weeks 5 and 6: no dose</td></tr>
<tr><td></td><td>1750 mg</td><td>Every 3 weeks starting at Week 7 onwards</td></tr>
<tr><td>≥ 80 kg</td><td>1750 mg</td><td>Weekly (total of 4 doses) from Weeks 1 to 4</td></tr>
</table></td></tr>
</table>

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		• Week 1: split infusion on Day 1 and Day 2 • Weeks 2 to 4: infusion on Day 1 Weeks 5 and 6: no dose
	2100 mg	Every 3 weeks starting at Week 7 onwards

Single agent:

Body weight at baseline [a]	Recommended Dose	Dosing Schedule
< 80 kg	1050 mg	Weekly (total of 5 doses) from Weeks 1 to 5 • Week 1: split infusion on Day 1 and Day 2 • Weeks 2 to 5: infusion on Day 1 • Week 6: no dose
		Every 2 weeks starting at Week 7 onwards
≥ 80 kg	1400 mg	Weekly (total of 5 doses) from Weeks 1 to 5 • Week 1: split infusion on Day 1 and Day 2 • Weeks 2 to 5: infusion on Day 1 Weeks 6: no dose
		Every 2 weeks starting at Week 7 onwards

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

NOTE:

- Administer premedications before each infusion as recommended.

VI. Billing Code/Availability Information

HCPCS Code:

- J9061 – Injection, amivantamab-vmjw, 2 mg; 1 billable unit = 2 mg

NDC:

- Rybrevant 350 mg/7 mL (50 mg/mL) solution as a single-dose vial: 57894-0501-xx

VII. References

1. Rybrevant [package insert]. Horsham, PA; Janssen Biotech, Inc.; March 2024. Accessed March 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for amivantamab. National Comprehensive Cancer Network, 2024. 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 March 2024.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Non-Small Cell Lung Cancer, Version 3.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®,

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4. Cho BC, Lee KH, Cho EK, et al. Amivantamab (JNJ-61186372), an anti-EGFR-MET bispecific antibody, in patients with EGFR exon 20 insertion (exon20ins)-mutated non-small cell lung cancer (NSCLC). DOI: 10.1200/JCO.2020.38.15_suppl.9512 Journal of Clinical Oncology 38, no. 15_suppl (May 20, 2020) 9512-9512.
5. 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.

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:

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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)
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

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