Medical Drug Clinical Criteria

Subject:	Rybrevant (amivantamab-vmjw), Rybrevant Faspro (amivantamab and hyaluronidase-lpuj)		
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Table of Contents

Overview | Coding | References

Clinical criteria | Document history

Overview

This document addresses the use of Rybrevant (amivantamab-vmjw) and Rybrevant Faspro (amivantamab and hyaluronidase-lpuj). Amivantamab is a bispecific epidermal growth factor (EGF) receptor-directed and mesenchymal-epithelial transition (MET) receptor-directed antibody used to treat non-small cell lung cancer (NSCLC). Binding to extracellular domains of EGF and MET receptors on the surface of tumor cells disrupts normal signaling and targets them for destruction by the immune system.

Rybrevant and Rybrevant Faspro have the following FDA approved indications:

- in combination with lazertinib, for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations
- 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 EFGR 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 a single agent for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations.

The National Comprehensive Cancer Network® (NCCN) provides recommendations with a category 1 or 2A level of evidence for the use of Rybrevant in alignment with the FDA indications in NSCLC, and includes use in NSCLC that has metastasized to the brain.

NCCN provides a 2A recommendation for the substitution of Rybrevant Faspro for IV amivantamab. NCCN states: amivantamab and hyaluronidase-lpuj subcutaneous injection may be substituted for IV amivantamab-vmjw. Amivantamab and hyaluronidase-lpuj has different dosing and administration instructions compared to amivantamab-vmjw.

Definitions and Measures

Line of Therapy:

- First-line therapy: The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
- Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (second-line therapy) are not effective or there is disease progression.

Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

Monoclonal antibody: A protein developed in the laboratory that can locate and bind to specific substances in the body and on the surface of cancer cells.

Progressive Disease (PD): Cancer that is growing, spreading, or getting worse.

Refractory Disease: Illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Rybrevant (amivantamab-vmjw) and Rybrevant Faspro (amivantamab and hyaluronidase-lpuj)

Requests for Rybrevant (amivantamab-vmjw) and Rybrevant Faspro (amivantamab and hyaluronidase-lpuj) may be approved if the following criteria are met:

I. Individual is under 19 years of age;

OR

II. Individual has a diagnosis of recurrent, advanced or metastatic non-small cell lung cancer (NSCLC) (Label, NCCN 2A); **AND**
III. Lung cancer has epidermal growth factor receptor (EGFR) exon 20 insertion mutations; **AND**
IV. Individual has disease progression on or after platinum-based chemotherapy; **AND**
V. Individual has not progressed on prior therapy with amivantamab (any formulation); **AND**
VI. Individual is using as a single agent;

OR

VII. Individual has a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (Label, NCCN 1); **AND**
VIII. Lung cancer has epidermal growth factor receptor (EGFR) exon 20 insertion mutations; **AND**
IX. Individual is using as first-line therapy in combination with carboplatin and pemetrexed;

OR

X. Individual has a diagnosis of recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC) (Label, NCCN 1); **AND**
XI. Lung cancer has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R mutations; **AND**
XII. Individual is using as subsequent therapy in combination with carboplatin and pemetrexed; **AND**
XIII. Individual has had disease progression on or after treatment with an EGFR tyrosine kinase inhibitor (e.g. osimertinib);

OR

XIV. Individual has a diagnosis of recurrent locally advanced or metastatic non-small cell lung cancer (NSCLC) (Label, NCCN 1, 2A); **AND**
XV. Lung cancer has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations; **AND**
XVI. Individual is using in combination with lazertinib for the following:
    A. As first line therapy; **OR**
    B. As continuation of therapy following disease progression on amivantamab (any formulation) and lazertinib; **OR**
    C. As subsequent therapy following disease progression on osimertinib for symptomatic systemic disease with multiple lesions; **OR**
    D. As subsequent therapy if progression on carboplatin or cisplatin/Osimertinib/pemetrexed if not previously given;

OR

XVII. Individual has a diagnosis of central nervous system cancer (NCCN 2A); **AND**
XVIII. Individual has a primary diagnosis of non-small cell lung cancer (NSCLC), and disease has metastasized to the brain; **AND**
XIX. Cancer has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutation; **AND**
XX. Individual is using in combination with lazertinib; **OR**
XXI. Individual is using in combination with carboplatin and pemetrexed;

OR

XXII. Individual has a diagnosis of NSCLC related leptomeningeal metastases (NCCN 2A); **AND**
XXIII. Disease is EGFR mutation positive (for exon 19 deletion or L858 substitution mutation); **AND**
XXIV. Individual is using in combination with lazertinib.

Requests for Rybrevant (amivantamab-vmjw) or Rybrevant Faspro (amivantamab and hyaluronidase-lpuj) may not be approved if the above criteria are not met and for all indications not included above.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS	
J9061	Injection, amivantamab-vmjw, 2 mg [Rybrevant]
J9062	Injection, amivantamab 5 mg and hyaluronidase-lpuj [Rybrevant Faspro]
ICD-10 Diagnosis	
C33	Malignant neoplasm of trachea
C34.00-C34.92	Malignant neoplasm of bronchus and lung
C79.31	Secondary malignant neoplasm of brain
C79.32	Secondary malignant neoplasm of cerebral meninges

Document History

Revised: 09/14/2026
Document History:

- 09/14/2026 – Select Review: Added new NCCN 2A indication for NSCLC related leptomeningeal metastases. Coding Reviewed: Added ICD-10-CM C79.32.
- 05/15/2026 – Annual Review: Removed reference to Rybrevant or Rybrevant Faspro within criteria to eliminate redundancy; updated references for progression on Rybrevant or Rybrevant Faspro to amivantamab (any formulation) for simplicity; clarified use in treatment of EGFR exon 19 or exon 21 L858R mutations disease progression on or after treatment with EGFR TKI; New step therapy for Rybrevant Faspro. Coding Reviewed: Removed HCPCS C9999 and J9999 for Rybrevant Faspro effective 6/30/26 and added J9062 effective 7/1/26.
- 02/20/2026 – Select Review: Wording and formatting criteria updates; Updated to add Rybrevant Faspro to criteria for all Rybrevant indications per NCCN recommendation to allow substitution of Faspro for IV Rybrevant; Updated NCCN 2A recommendations for use in combination with Lazertinib to include disease progression on Osimertinib and disease progression on carboplatin or cisplatin/Osimertinib/pemetrexed. Coding Reviewed: Added HCPCS NOC C9399 and J9999 for Rybrevant Faspro.
- 08/15/2025 – Select Review: Add use in NSCLC with brain metastases per NCCN. Coding Reviewed: Added ICD-10-CM C79.31.
- 05/16/2025 – Annual Review: Remove select exon 21 mutations from subsequent therapy indication per NCCN and label; update references. Coding Reviewed: Updated description for HCPCS J9061.
- 11/15/2024 – Select Review: Add new FDA indication for use of Rybrevant as continuation of therapy following disease progression on Rybrevant and Lazertinib. Coding Reviewed: No changes.

- 09/09/2024 – Select Review: Add new indication as first line therapy in combination with Lazertinib. Coding Reviewed: Add ICD-10-CM C33 and revised naming of C34.00-C34.92 to Malignant neoplasm of bronchus and lung.
- 05/17/2024 – Annual Review: Add use as subsequent therapy after progression on osimertinib for non-small cell lung cancer with exon 19 deletion or certain exon 21 mutations; add recurrent disease to first-line use; update references. Coding Reviewed: No changes.
- 03/11/2024 – Select Review: Add new FDA approved indication for first-line therapy of NSCLC. Coding Reviewed: No changes.05/19/2023 – Annual Review: Minor wording and formatting updates. Coding Reviewed: No changes.
- 05/20/2022 – Annual Review: Update criteria to include recurrent disease and no prior progression on Rybrevant per NCCN. Coding Reviewed: Added ICD-10-CM C34.00, C34.01, C34.02. Revised ICD-10-CM C34.10-C34.92.
- 06/14/2021 – Annual Review: Add new clinical criteria document for Rybrevant. Coding Reviewed: Added HCPCS J9999. All diagnoses pend. Effective 10/1/2021 Added HCPCS C9083 and ICD-10-CM C34.00-C34.92. Coding Reviewed 1/1/2022-Removed HCPCS J9999, C9083. Added HCPCS J9061. Removed all diagnoses pend.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2026; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2026 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on March 25, 2026.
    a. Central Nervous System Cancers. V3.2025. Revised December 5, 2025.
    b. Non-Small Cell Lung Cancer. V5.2026. Revised March 13, 2026.

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