Medical Drug Clinical Criteria

Subject:	Rybrevant (amivantamab-vmjw)		
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Overview

This document addresses the use of Rybrevant (amivantamab-ymjw). Rybrevant 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 is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR exon 20 insertion mutations: as a first-line therapy in combination with carboplatin and paclitaxel; or for those whose disease has progressed on or after platinum-based chemotherapy. EGFR exon 20 mutations, present in about 2 to 3% of NSCLCs, are a heterogeneous group of mutations that may or may not be responsive to targeted therapy. Rybrevant is also approved in combination with Lazertinib as first line therapy for lung cancer with exon 19 deletions or exon 21 (L858R) substitution mutations. The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 1 or 2A level of evidence for the use of Rybrevant. NCCN recommends the use of Rybrevant as first-line or subsequent therapy for NSCLC with EGFR exon 20 insertion mutations according to FDA approved indications. NCCN also gives a category 1 recommendation for Rybrevant as subsequent therapy for NSCLC with EGFR exon 19 deletion or exon 21 L858R S768I, L861Q, and/or G719X mutations which has progressed on therapy with osimertinib.

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)

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

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

OR

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

OR

IX. Individual has a diagnosis of recurrent, advanced, or metastatic Non-small Cell Lung Cancer (NSCLC) (NCCN 1); **AND**
X. Lung cancer has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R S768I, L861Q, and/or G719X mutations; **AND**
XI. Individual is using Rybrevant (amivantamab-vmjw) as subsequent therapy in combination with carboplatin and pemetrexed; **AND**
XII. Individual has had disease progression on osimertinib;

OR

XIII. Individual has a diagnosis of locally advanced or metastatic Non-small Cell Lung Cancer (NSCLC) (Label); **AND**
XIV. Lung cancer has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations; **AND**
~~XII.~~XV. Individual is using Rybrevant (amivantamab-vmjw) as first-line therapy in combination with Lazertinib.

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Requests for Rybrevant (amivantamab-vmjw) 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, 10 mg [Rybrevant]
ICD-10 Diagnosis	
C33	Malignant neoplasm of trachea
C34.00-C34.92	Malignant neoplasm of bronchus and lung
~~C34.00~~	~~Malignant neoplasm of unspecified main bronchus~~
~~C34.01~~	~~Malignant neoplasm of left main bronchus~~
~~C34.02~~	~~Malignant neoplasm of right main bronchus~~
~~C34.10-C34.92~~	~~Malignant neoplasm of main bronchus~~

Document History

Revised: 09/09/2024
Document History:

- 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.; 2024; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on March 12, 2024.
    a. Non-Small Cell Lung Cancer. V3.2024. Revised March 12, 2024

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.