Clinical Criteria

Subject:	Rybrevant (amivantamab-ymjw)		
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Status:	~~New~~Revised	**Last Review Date:**	~~06/14/2021~~05/20/2022

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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 whose disease has progressed on or after platinum-based chemotherapy. It is under accelerated approval for this indication; and continued approval may be contingent upon verification of clinical benefit in confirmatory trials. Rybrevant differs from other FDA approved oral EGFR tyrosine kinase inhibitors (TKIs) such as osimertinib, erlotinib or gefitinib as they target different EGFR sensitizing mutations: exon 19 deletions or exon 21 (L858R) substitution mutations. 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. Individuals in the efficacy population from the clinical trial for Rybrevant were genetically evaluated using the FDA approved companion diagnostic test, Guardant360. The phase 1 clinical trial evaluated for FDA approval included 81 patients with NSCLC previously treated with platinum-based chemotherapy. The overall response rate was 40% with a median duration of response of 11.1 months. Rybrevant is currently being studied in phase 3 trials in combination with a novel oral third generation tyrosine kinase inhibitor, and in combination with platinum-based chemotherapy. Currently, it is approved for use as a single agent. The National Comprehensive Cancer Network® (NCCN) guidelines recommend the use of Rybrevant in recurrent, advanced or metastatic NSCLC with EGFR exon 20 insertion mutations as subsequent therapy (if not used previously).

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 ~~locally~~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, with test results confirmed; **AND**
III. Individual has demonstrated disease progression on or after platinum-based chemotherapy; **AND**
IV. Individual has not progressed on prior therapy with Rybrevant (amivantamab-vmjw); **AND**
~~IV.~~V. Individual is using Rybrevant (amivantamab-vmjw) as a single agent.

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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

C34.10-C34.92	Malignant neoplasm of main bronchus

Document History

Revised: 05/20/2022
Document History:

- 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 C34.10-C34.92. Removed ICD-10-CM C34.00-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. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: April 1, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on April 1, 2022.
    a. Non-Small Cell Lung Cancer. V3.2022. Revised March 16, 2022.

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.