CLINICAL GUIDELINES FOR MEDICAL NECESSITY

MEDICAL POLICY

Amivantamab-vmjw (Rybrevant®)

Version: 1.0

EFFECTIVE DATE: 1/1/2024

NantHealth® | Eviti®

Please note the following:

Amivantamab-ymjw (Rybrevant®)

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Please refer to the CMS website at http://www.cms.gov for additional information.

Note: For Medicaid members/enrollees, circumstances when state Medicaid coverage provisions conflict with the coverage provisions within this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Amivantamab-ymjw (Rybrevant): Discussion

Amivantamab-vmjw is a fully human epidermal growth factor receptor (EGFR) and mesenchymal epithelial transition (MET) bispecific antibody with an immune cell-directing activity designed to engage two distinct driver pathways in non-small cell lung cancer (NSCLC). By binding to each receptor's extracellular domain, amivantamab-vmjw can inhibit ligand binding and, in exon 20 insertion mutation models, degradation of EGFR and MET. EGFR is a signaling pathway that regulates cell differentiation, proliferation, migration, angiogenesis, and apoptosis. MET is a reversible biological process that involves the transition from motile, multipolar, or spindle-shaped mesenchymal cells to planar arrays of polarized cells called epithelia. The presence of EGFR and MET on the surface of tumor cells also allows for the targeting of these cells for destruction by immune effector cells, such as natural killer cells and macrophages, through antibody-dependent cellular cytotoxicity (ADCC) and trogocytosis mechanisms, respectively.[1,2.]

Amivantamab-vmjw is approved by the Food and Drug Administration (FDA) for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy. [2]

The NCCN NSCLC Panel recommends testing for EGFR exon 20 insertion mutations in all patients with metastatic nonsquamous NSCLC or NSCLC NOS based on data showing the efficacy of several agents as subsequent therapy options for patients with EGFR exon 20 insertion-positive metastatic NSCLC. EGFR exon 20 insertion mutation testing can be considered in patients with metastatic squamous cell carcinoma. The NCCN NSCLC panel recommends amivantamab-vmjw as a subsequent therapy option for patients with EGFR exon 20 insertion mutation-positive metastatic NSCLC and disease progression on or after systemic therapy options based on clinical trial data and FDA approval. [3]

The National Comprehensive Cancer Network (NCCN) endorses amivantamab-vmjw in the following cancer types: non-small cell lung cancer. [3]

Amivantamab-vmjw: Definitions

- **Antibody-Dependent Cell-Mediated Cytotoxicity (ADCC) -** Antibody-dependent cellular cytotoxicity (ADCC) is a cytolytic process that is dependent on the cooperative interaction of several different cellular and humoral constituents of the immune system.
- **Food and Drug Administration (FDA)** – The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
- **National Comprehensive Cancer Network (NCCN) -** An alliance of thirty-two leading cancer centers devoted to patient care, research, and education. The NCCN guidelines are utilized for Radiation Therapy and Medical Oncology standards. NCCN consensus clinical standards are periodically updated and NantHealth, Inc. reviews these and updates its policies within a timely manner.

Amivantamab-vmjw: Policy

Amivantamab-vmjw will be considered for coverage when the following criteria are met:

Non-Small Cell Lung Cancer (Adenocarcinoma (with mixed subtypes), Large cell carcinoma, Squamous cell carcinoma)

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Subsequent therapy (if not previously received; may be used if previously received mobocertinib) as a single agent for EGFR exon 20 insertion mutation positive recurrent, advanced, or metastatic disease [3]

Note: Coverage of amivantamab-vmjw will be provided for an FDA-approved indication or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1, 2A, or 2B recommendation OR when all criteria are met.

Authorization Period and Renewal Criteria

1. Initial Authorization Period: 12 months
2. Renewal Criteria: No evidence of disease progression or unacceptable toxicity
3. Renewal Authorization Period: 12 months

Amivantamab-vmjw: References

1. Amivantamab in EGFR Exon 20 Insertion–Mutated Non–Small-Cell Lung Cancer Progressing on Platinum Chemotherapy: Initial Results from the CHRYSALIS Phase I

Study. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8791812. Accessed May 16, 2023.
2. Package Insert Amivantamab-vmjw (Rybrevant). https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761210s002lbl.pdf. Accessed May 16, 2023.
3. National Comprehensive Cancer Network Guidelines. Non-Small Cell Lung Cancer (Version 3.2023). https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed May 16, 2023.

Amivantamab-vmjw: Coding (CPT®, ICD- 10 and HCPCS) *

*Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all-inclusive and is subject to updates. In addition, the codes listed are not a guarantee of payment.

CODE	DESCRIPTION
C34.90- C34.92-	Non-small cell lung cancer
C78.00- C78.02	Secondary Malignant Neoplasm of Unspecified Lung
J9061	Amivantamab-vmjw (Rybrevant)

Amivantamab-vmjw: Revision and Review History

No.	Description	Date(s)
1	Original Effective Date:	1/1/2024
2	Policy Review Dates:	5/12/2023
3	Policy Revision Dates:	
4	Department Owner:	Medical Affairs
5	NH Advisory Committee Approval Dates:	6/27/2023
6	Revision Changes:	