Medical Policy:

Rybrevant® (amivantamab-vmjw) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.342	February 19, 2025	September 14, 2021

Definitions

Rybrevant, a bispecific epidermal growth factor receptor (EGFR)-directed and mesenchymal epithelial transition (MET) receptor-directed antibody, is indicated for the treatment of adults with locally advanced or metastatic non-small cell lung cancer with EGFR exon 20 insertion mutations, as detected by a FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

Length of Authorization

Coverage will be provided for 1 year and may be renewed.

Dosing Limits [Medical Benefit]

Dosing. Approve one of the following dosing regimens (A or B):

A. First-line treatment:

i. Weight < 80 kg: Approve up to 1,400 mg administered by intravenous infusion once weekly for the first four doses, then approve up to 1,750 mg administered intravenously no more frequently than once every 3 weeks; **OR**

Note: The initial dose is divided and given on two consecutive days in the first week.

ii. Weight ≥ 80 kg: Approve up to 1,750 mg administered by intravenous infusion once weekly for the first four doses, then approve up to 2,100 mg administered intravenously no more frequently than once every 3 weeks; **OR**

Note: The initial dose is divided and given on two consecutive days in the first week.

B. Subsequent treatment:

i. Weight < 80 kg: Approve up to 1,050 mg administered by intravenous infusion no more frequently than once weekly; **OR**

Note: The initial dose is divided and given on two consecutive days in the first week.

ii. Weight ≥ 80 kg: Approve up to 1,400 mg administered by intravenous infusion no more frequently than once weekly.

Note: The initial dose is divided and given on two consecutive days in the first week.

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

Guideline

I. Initial Approval Criteria

1. **Non-Small Cell Lung Cancer:** Approve if the patient meets all the following criteria:
   A. Patient is ≥ 18 years of age; **AND**
   B. 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**
      i. Used in combination with carboplatin and pemetrexed in patients with nonsquamous histology; **AND**
         a. Used as first-line therapy; **AND**
            1.) Patient has epidermal growth factor receptor (EGFR) exon 20 insertion mutation positive disease as detected by an FDA-approved or CLIA compliant test❖; **OR**
         b. Used as subsequent therapy; **AND**
            1.) 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**
            2.) Used following disease progression on osimertinib for symptomatic systemic disease with multiple lesions; **OR**
      ii. Used as a single agent; **AND**
         a. Used as subsequent therapy; **AND**
         b. 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*

II. Renewal Criteria:

1. **Non-Small Cell Lung Cancer:**
   A. Patient has experienced a clinical response as determined by the prescribing physician; **AND**
   B. Patient has not experienced unacceptable toxicity from the drug. (e.g- infusion related reactions, Interstitial lung disease**,** Keratitis, Uveitis**,** etc)

Applicable Procedure Codes

Code	Description

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

Applicable NDCs

Code	Description
57894-0501-01	Injection for intravenous infusion, 350mg/7ml (50mg/ml), in a single use vial

ICD-10 Diagnoses

Code	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

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/19/2025	Annual Review: added max dosing units. Initial Criteria: Non-Small Cell Lung Cancer: Removed or reworded the following: "Patient has a diagnosis of 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; AND Medication is prescribed by, or in consultation with, an oncologist; AND Patient's disease has progressed on or after platinum-based chemotherapy OR *Note: Examples of platinum chemotherapy include cisplatin, carboplatin, and oxaliplatin.* Rybrevant is used in combination with carboplatin and pemtrexed as first line treatment" Added: "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 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 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❖ "
EmblemHealth & ConnectiCare	5/29/2024	Revision: updated to include first line treatment of NSCLC by adding: "**OR** Rybrevant is used in combination with carboplatin and pemtrexed as first line treatment" Updated dosing limits
EmblemHealth & ConnectiCare	1/9/2024	Annual Review: No Criteria changes
EmblemHealth & ConnectiCare	5/9/2023	Annual Review: Removed Codes: C9083 and J9999, added code J9061, removed ICD-10 codes D59.5, added C33 and Z85.118
EmblemHealth & ConnectiCare	1/11/2023	Transferred to New Template
EmblemHealth & ConnectiCare	9/14/2021	New Policy

References

1. Rybrevant™ intravenous infusion [prescribing information]. Horsham, PA: Janssen Biotech, Inc. Updated July 26, 2021. Accessed August 2, 2021.
2. Rybrevant™ intravenous infusion. IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: https://www.micromedexsolutions.com. Updated May 26, 2021. Accessed July 30, 2021.