

Medical Policy:

Rybrevant® (amivantamab-vmjw) Intravenous

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

Medical Guideline Disclaimer Property of EmblemHealth. All rights reserved.

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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 \geq 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 \geq 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 \geq 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 \blacklozenge ; **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 \blacklozenge ; **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 \blacklozenge

\blacklozenge *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 <i>Note: Examples of platinum chemotherapy include cisplatin, carboplatin, and oxaliplatin.</i> Rybrevant is used in combination with carboplatin and pemetrexed 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 pemetrexed 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.