# PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology (Injectable) – Rybrevant Prior Authorization Policy
- Rybrevant™ (amivantamab-vmjw intravenous infusion – Janssen)

**REVIEW DATE:** 03/13/2024; selected revision 08/28/2024

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## OVERVIEW

Rybrevant, a bispecific epidermal growth factor receptor (EGFR)-directed and mesenchymal epithelial transition (MET) receptor-directed antibody, is indicated for the treatment of locally advanced or metastatic **non-small cell lung cancer** (NSCLC):[1]

- In combination with Lazcluze™ (lazertinib tablets) for the first-line treatment of adults with *EGFR* exon 19 deletions, or exon 21 *L858R* substitution mutations, as detected by an FDA-approved test.
- In combination with carboplatin and pemetrexed for the first-line treatment of adults with *EGFR* exon 20 insertion mutations, as detected by an FDA-approved test.
- As a single agent, in adults with EGFR exon 20 insertion mutation, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

## Guidelines

The National Comprehensive Cancer Network (NCCN) non-small cell lung cancer guidelines (version 8.2024 – August 23, 2024) recommend Rybrevant for the first-line treatment, in combination with carboplatin and pemetrexed and subsequent treatment, as a single agent, of EGFR exon 20 insertion mutation positive recurrent, advanced, or metastatic NSCLC.[2,3] In addition, Rybrevant is recommended for the subsequent treatment of recurrent, advanced, or metastatic NSCLC with EGFR exon 19 deletion, exon 21 *L858R*, or EGFR *S768I*, *L861Q* and/or *G719X* mutation, in combination with carboplatin and pemetrexed, following disease progression on Tagrisso® (osimertinib tablets).

## POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Rybrevant. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Rybrevant as well as the monitoring required for adverse events and long-term efficacy, approval requires Rybrevant to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Automation:** None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Rybrevant is recommended in those who meet the following criteria:

### FDA-Approved Indication

1. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has locally advanced or metastatic disease; AND
   - **C)** Patient meets ONE of the following (i or ii):

- **i.** Patient has ONE of the following (a, b, or c):
  - **a)** Epidermal growth factor receptor exon 20 insertion mutations, as detected by an approved test; OR
  - **b)** EGFR exon 19 deletions, as detected by an approved test; OR
  - **c)** EGFR exon 21 L858R substitution mutations, as detected by an approved test; OR
- **ii.** Patient meets BOTH of the following (a and b):
  - **a)** Medication is used as subsequent therapy; AND
  - **b)** Patient has EGFR S768I, L861Q, and/or G719X mutation; AND

**D)** The medication is prescribed by or in consultation with an oncologist.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Rybrevant is not recommended in the following situations:

**1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Rybrevant intravenous infusion [prescribing information]. Horsham, PA: Janssen; August 2024.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 26, 2024. Search term: amivantamab.
3. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 8.2024 – August 23, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 26, 2024.