| Reference number(s) |
| --- |
| 4745-A |

# Specialty Guideline Management
# Rybrevant

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Rybrevant | amivantamab-vmjw |

## Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-Approved Indications[1]

- Rybrevant is indicated in combination with lazertinib for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test.
- Rybrevant is indicated in combination with carboplatin and pemetrexed for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor.
- Rybrevant is indicated in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, as detected by an FDA-approved test.

- Rybrevant is indicated as a single agent for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

## Compendial Uses[2]

- First-line therapy for recurrent, advanced, or metastatic EGFR exon 20 insertion mutation positive nonsquamous NSCLC.
- Subsequent therapy for recurrent, advanced, or metastatic EGFR exon 20 insertion mutation positive NSCLC.
- Subsequent therapy for recurrent, advanced, or metastatic EGFR exon 19 deletion or exon 21 L858R mutation positive nonsquamous NSCLC.
- Recurrent, advanced, or metastatic EGFR exon 19 deletion or exon 21 L858R mutation positive NSCLC in combination with lazertinib.

All other indications are considered experimental/investigational and not medically necessary.

# Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Test results showing the presence of EGFR exon 20 insertion mutations, where applicable.
- Test results showing the presence of EGFR exon 19 deletion or exon 21 L858R mutations, where applicable.

# Coverage Criteria

## Non-Small Cell Lung Cancer (NSCLC)[1,2]

- Authorization of 12 months may be granted for first-line treatment of advanced, recurrent, or metastatic non-small cell lung cancer (NSCLC) and either of the following criteria are met:
    - Member has nonsquamous NSCLC with epidermal growth factor receptor (EGFR) exon 20 insertion mutations and the requested medication will be used in combination with carboplatin and pemetrexed or
    - Member has EGFR exon 19 deletion or exon 21 L858R substitution mutation positive disease and the requested medication will be used in combination with lazertinib (Lazcluze).
- Authorization of 12 months may be granted for subsequent treatment of advanced, recurrent, or metastatic NSCLC when either of the following criteria are met:
    - Member has EGFR exon 20 insertion mutation positive disease and both of the following criteria are met:
        - Disease has progressed on or after platinum based chemotherapy and

        - The requested medication will be used as a single agent
    - Member has nonsquamous NSCLC with EGFR exon 19 deletion or exon 21 L858R mutations and both of the following criteria are met:
        - Disease has progressed on or after treatment with Tagrisso (osimertinib) and
        - The requested medication will used in combination with carboplatin and pemetrexed.

# Continuation of Therapy

## Non-small cell lung cancer (NSCLC)[1,2]

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for EGFR positive NSCLC when any of the following criteria are met:

- There is no evidence of unacceptable toxicity or disease progression while on the current regimen.
- The member is requesting the medication in combination with lazertinib (Lazcluze) and there is no evidence of unacceptable toxicity while on the current regimen.

# References

1. Rybrevant [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed February 26, 2025.