 Draft Revised Policy: Do Not Implement

Amivantamab-vmjw (Rybrevant™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

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

- 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

- 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 ~~or EGFR S768I, L861Q, and/or G719X~~ 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 ~~or EGFR S768I, L861Q, and/or G719X~~ mutations, where applicable.

COVERAGE CRITERIA

Non-Small Cell Lung Cancer (NSCLC)

- Authorization of 12 months may be granted for first-line treatment of advanced, recurrent, or metastatic ~~nonsquamous~~ non-small cell lung cancer (NSCLC) ~~with epidermal growth factor receptor (EGFR) exon 20 insertion mutations when used in combination with carboplatin and pemetrexed.~~ 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 ~~with EGFR exon 20 insertion mutations, whose disease has progressed on or after platinum-based chemotherapy, when used as a single agent~~ 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.
- ~~Authorization of 12 months may be granted for subsequent treatment of advanced, recurrent, or metastatic nonsquamous NSCLC with EGFR exon 19 deletion or exon 21 L858R or EGFR S768I, L861Q, and/or G719X mutations, whose disease has progressed on Tagrisso (osimertinib), when used in combination with carboplatin and pemetrexed.~~
- ~~Authorization of 12 months may be granted for first-line treatment of recurrent, advanced, or metastatic NSCLC with EGFR exon 19 deletion or exon 21 L858R substitution mutations when used in combination with lazertinib (Lazcluze).~~
- ~~Authorization of 12 months may be granted for treatment of locally advanced or metastatic NSCLC with EGFR exon 19 deletion or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor, when used in combination carboplatin and pemetrexed.~~

CONTINUATION OF THERAPY

Non-Small Cell Lung Cancer (NSCLC)

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.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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.

EFFECTIVE DATE

ID_CHS