Amivantamab and Hyaluronidase-lpuj (Rybrevant Faspro™)

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.

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 Faspro 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 Faspro 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 Faspro 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 Faspro 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

- 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.
- Treatment of brain metastases from EGFR exon 19 deletion or exon 21 L858R mutation positive NSCLC in combination with lazertinib or carboplatin and pemetrexed.
- 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.

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

DOCUMENTATION

This document has been classified as public information

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

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

COVERAGE CRITERIA

Non-Small Cell Lung Cancer (NSCLC)

With Epidermal Growth Factor Receptor (EGFR) Exon 19 Deletion or Exon 21 L858R Mutation

Authorization of 12 months may be granted for treatment of advanced, recurrent, or metastatic NSCLC when used in combination with lazertinib (Lazcluze).

Authorization of 12 months may be granted for treatment of brain metastases from NSCLC when used in combination with lazertinib (Lazcluze) or carboplatin and pemetrexed.

Authorization of 12 months may be granted for subsequent treatment of advanced, recurrent, or metastatic nonsquamous NSCLC when either of the following criteria is met:

- The requested medication will be used in combination with carboplatin and pemetrexed following disease progression on osimertinib (Tagrisso) or lazertinib (Lazcluze).
- The requested medication will be used in combination with lazertinib following disease progression on osimertinib (Tagrisso), pemetrexed, or platinum based chemotherapy.

With EGFR Exon 20 Insertion Mutation

Authorization of 12 months may be granted for treatment of advanced, recurrent, or metastatic NSCLC when either of the following criteria is met:

- The requested medication will be used as first-line treatment in combination with carboplatin and pemetrexed for nonsquamous disease.
- The requested medication will be used as subsequent treatment as a single agent.

CONTINUATION OF THERAPY

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

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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 Faspro [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2026.
2. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 3, 2026.

EFFECTIVE DATE 12/1/2026

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