Reference number(s)
7331-A

Standard Medicare Part B Management Rybrevant Faspro

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 Faspro	amivantamab and hyaluronidase-lpuj

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 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.

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- 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[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 will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all initial requests:

- 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 nonsquamous non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations and the requested medication will be used in combination with carboplatin and pemetrexed.
- Authorization of 12 months may be granted for treatment of advanced, recurrent, or metastatic NSCLC with 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:

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  - 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 all members (including new members) who are continuing with the requested therapy when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat non-small cell lung cancer (NSCLC)
- The member is receiving benefit from therapy. Benefit is defined as:
  - No evidence of unacceptable toxicity while on the current regimen and
  - No evidence of disease progression while on the current regimen

Authorization of 12 months may be granted for all members (including new members) who are continuing with the requested therapy when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication in combination with lazertinib (Lazcluze)
- The requested medication is being used to treat NSCLC
- The member is receiving benefit from therapy. Benefit is defined as: no evidence of unacceptable toxicity while on the current regimen

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Rybrevant Faspro.
- The available compendium
  - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
  - Micromedex DrugDex
  - American Hospital Formulary Service- Drug Information (AHFS-DI)
  - Lexi-Drugs
  - Clinical Pharmacology
- NCCN Guideline: Non-small cell lung cancer

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After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Rybrevant Faspro are covered including:

- 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

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Rybrevant Faspro as 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 and recurrent, advanced, or metastatic EGFR exon 19 deletion or exon 21 L858R mutation positive NSCLC in combination with lazertinib can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Rybrevant Faspro [package insert]. Horsham, PA: Janssen Biotech, Inc.; December 2025.
2. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 6, 2026.

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