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POLICY Document for RYBREVANT FASPRO

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall, clinically appropriate use. This document provides specific information to each of the three sections of the overall policy.

Section 1: Site of Care

- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care

Site of Care Criteria
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.

Brand Name	Generic Name	Dosage Form
Rybrevant Faspro	amivantamab and hyaluronidase-lpuj	subcutaneous

Criteria For Approval For Administration In Outpatient Hospital Setting

This policy provides coverage for administration of Rybrevant Faspro in an outpatient hospital setting for up to 45 days when a member is new to Rybrevant Faspro therapy or is reinitiating therapy after not being on therapy for at least 6 months.

This policy provides coverage for administration of Rybrevant Faspro in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

- The member has experienced an adverse reaction that did not respond to conventional interventions (e.g., acetaminophen, steroids, diphenhydramine, fluids, or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after administration
- The member is medically unstable (e.g., respiratory, cardiovascular, or renal conditions).
- The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of drug administration AND the patient does not have access to a caregiver.
- The member is receiving provider administered combination chemotherapy.
- Alternative administration sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home.
- The member is less than 14 years of age.

For situations where administration of Rybrevant Faspro does not meet the criteria for outpatient hospital administration, coverage for Rybrevant Faspro is provided when administered in alternative sites such as physician office, home infusion or ambulatory care.

Required Documentation

The following information is necessary to initiate the site of care prior authorization review (where applicable):

- Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after administration
- Medical records supporting the member is medically unstable
- Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
- Medical records supporting the member is receiving provider administered combination therapy
- Records supporting alternative administration sites are greater than 30 miles from the member's home
- Medical records supporting the member is new to therapy

Section 2: Clinical Criteria

Specialty Guideline Management
Rybrevant Faspro

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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.
- 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 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 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:
        - Disease has progressed on or after platinum based chemotherapy.
        - 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).
        - 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 epidermal growth factor receptor (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

SECTION 1

1. Rybrevant Faspro [package insert]. Horsham, PA: Janssen Biotech, Inc.; December 2025.

SECTION 2

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