

Clinical Policy: Amivantamab-vmjw (Rybrevant)

Reference Number: ERX.SPA.444

Effective Date: 06.15.21

Last Review Date: 08.22

Line of Business: Commercial, Medicaid

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

Description

Amivantamab-vmjw (Rybrevant[™]) is a bispecific EGF receptor-directed and MET receptor-directed antibody.

FDA Approved Indication(s)

Rybrevant is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions[™] that Rybrevant is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (must meet all):

1. Diagnosis of recurrent, locally advanced or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Disease is positive for EGFR exon 20 insertion mutations;
5. Member has progressed on or after platinum-based therapy (see *Appendix B*);
6. Request meets one of the following (a or b):*
 - a. Dose does not exceed the appropriate weight-based dose (i or ii) per week for 4 weeks, then every 2 weeks thereafter (see *section V for dosing regimen*):
 - i. Body weight < 80 kg: 1,050 mg (3 vials);
 - ii. Body weight \geq 80 kg: 1,400 mg (4 vials);
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Non-Small Cell Lung Cancer (must meet all):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Rybrevant for NSCLC and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
 - a. New Dose does not exceed the appropriate weight-based dose (i or ii) every 2 weeks (see section V for dosing regimen):
 - i. Body weight < 80 kg: 1,050 mg (3 vials);
 - ii. Body weight ≥ 80 kg: 1,400 mg (4 vials);
 - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

EGFR: epidermal growth factor receptor
 FDA: Food and Drug Administration
 NSCLC: non-small cell lung cancer

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
platinum-based chemotherapy (e.g., cisplatin, carboplatin)	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NSCLC	Weight-based dose IV weekly for 4 weeks, with the initial dose as a split infusion in Week 1 on Day 1 and Day 2, then every 2 weeks thereafter: Week 1, day 1: <ul style="list-style-type: none"> • Body weight < 80 kg: 350 mg (1 vial) 	See regimen

Indication	Dosing Regimen	Maximum Dose
	<ul style="list-style-type: none"> Body weight \geq 80 kg: 350 mg (1 vial) Week 1, day 2: <ul style="list-style-type: none"> Body weight $<$ 80 kg: 700 mg (2 vials) Body weight \geq 80 kg: 1050 mg (3 vials) Week 2 and thereafter: <ul style="list-style-type: none"> Body weight $<$ 80 kg: 1,050 mg (3 vials) Body weight \geq 80 kg: 1,400 mg (4 vials) 	

VI. Product Availability

Solution for injection in a single-dose vial: 350 mg/7 mL (50 mg/mL)

VII. References

1. Rybrevant Prescribing Information. Horsham, PA: Janssen Biotech, Inc.; December 2021. Available at: <https://www.rybrevant.com>. Accessed May 3, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 3, 2022.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer. Version 3.2022. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed May 3, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	06.15.21	08.21
3Q 2022 annual review: no significant changes; per NCCN compendium added additional option for recurrent NSCLC; references reviewed and updated.	05.03.22	08.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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