Clinical Policy: Amivantamab-vmjw (Rybrevant)

Reference Number: PA.CP.PHAR.544
Effective Date: 08/2022
Last Review Date: 07/2023

Coding Implications
Revision Log

Description

Amivantamab-vmjw (Rybrevant®) is a bispecific epidermal growth factor (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.

It is the policy of PA Health & Wellness® 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 ≥ 18 years;
4. Disease is positive for epidermal growth factor receptor (EGFR) exon 20 insertion mutations;
5. Member has progressed on or after platinum-based therapy;
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:
      i. Body weight < 80 kg: 1,050 mg (3 vials);
      ii. Body weight ≥ 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*).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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:
      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*).

Approval duration: 12 months

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

EGFR: epidermal growth factor receptor
FDA: Food and Drug Administration
MET: mesenchymal-epithelial transition
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: • Body weight < 80 kg: 350 mg (1 vial) • Body weight ≥ 80 kg: 350 mg (1 vial) Week 1, day 2: • Body weight < 80 kg: 700 mg (2 vials) • Body weight ≥ 80 kg: 1,050 mg (3 vials) Week 2 and thereafter: • Body weight < 80 kg: 1,050 mg (3 vials) • Body weight ≥ 80 kg: 1,400 mg (4 vials)	See regimen

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.; November 2022. Available at: https://www.Rybrevant.com/. Accessed May 8, 2023.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 8, 2023.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer. Version 3.2023. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed May 8, 2023.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9061	Injection, amivantamab-vmjw, 2 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07/2022	
3Q 2023 annual review: no significant changes; references reviewed and updated.	07/2023	