Clinical Policy: Amivantamab-vmjw (Rybrevant)

Reference Number: PA.CP.PHAR.544
Effective Date: 08/2022
Last Review Date: 04/2024

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:

- In combination with carboplatin and pemetrexed 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 20 insertion mutations, as detected by an FDA-approved test
- 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

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, advanced or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is positive for one of the following (a or b):
   a. EGFR exon 20 insertion mutations, and prescribed for one of the following uses (i or ii):
      i. As first line therapy in combination with carboplatin and pemetrexed;
      ii. As a single agent for disease that has progressed on or after platinum-based therapy;
   b. Other sensitizing EGFR mutation (e.g., exon 19 deletion, exon 21 point mutation [L858R, L861Q], exon 18 point mutation [G719X], exon 20 point mutation [S768I]), AND all of the following (i, ii, and iii):
      i. Progression on Tagrisso®;

ii. Presence of symptomatic systemic disease with multiple lesions;
iii. Prescribed in combination with carboplatin and pemetrexed;

5. Request meets one of the following (a, b or c):
   a. Single agent: Dose does not exceed the appropriate weight-based dose (i or ii) per week for 4-5 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. Prescribed in combination with carboplatin and pemetrexed: Dose does not exceed the appropriate weight-based dose (1 or 2) per week for 4 weeks (i), then every 3 weeks thereafter (ii) (*see section V for dosing regimen*):
      i. For the first four weeks (a or b):
         a. Body weight < 80 kg: 1,400 mg (4 vials);
         b. Body weight ≥ 80 kg: 1,750 mg (5 vials);
      ii. For every 3 weeks thereafter (a or b):
         a. Body weight < 80 kg: 1,750 mg (5 vials);
         b. Body weight ≥ 80 kg: 2,100 mg (6 vials);
   c. 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, b or c):
   a. Single agent: 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. Prescribed in combination with carboplatin and pemetrexed: New dose does not exceed the appropriate weight-based dose (i or ii) every 3 weeks (*see section V for dosing regimen)*:
      i. Body weight < 80 kg: 1,750 mg (5 vials);
      ii. Body weight ≥ 80 kg: 2,100 mg (6 vials);
   c. 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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Platinum-based chemotherapy (e.g., cisplatin, carboplatin)	Varies	Varies
Tagrisso® (osimertinib)	80 mg PO QD	80 mg/day

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	In combination with carboplatin and <u>pemetrexed:</u> 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 3 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: 1,050 mg (3 vials) • Body weight ≥ 80 kg: 1,400 mg (3 vials)	See regimen

Indication	Dosing Regimen	Maximum Dose
	Week 2 to 4: • Body weight < 80 kg: 1,400 mg (4 vials) • Body weight ≥ 80 kg: 1,750 mg (5 vials) Week 7 and thereafter: • Body weight < 80 kg: 1,750 mg (5 vials) • Body weight ≥ 80 kg: 2,100 mg (6 vials) Single agent: 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)	

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.; March 2024. Available at: https://www.Rybrevant.com/. Accessed March 25, 2024.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed March 25, 2024.
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 March 25, 2024.

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
Policy created	07/2022

Reviews, Revisions, and Approvals	Date
3Q 2023 annual review: no significant changes; references reviewed and updated.	07/2023
RT4: added criteria for new indication of first-line treatment of adults with NSCLC; added monotherapy criterion for NSCLC with EGFR exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy per Prescribing Information and NCCN; removed “locally” as qualifying advanced NSCLC per NCCN; for Rybrevant prescribed as a single agent corrected initial dosing to be weekly for 5 weeks instead of 4 weeks.	04/2024