amivantamab-vmjw (Rybrevant™)	Place of Service Office Administration Infusion Center Administration Home Infusion Administration Outpatient Facility Infusion Administration HCPCS: J9061 per 2 mg

Condition listed in policy (*see criteria for details*)

- Non-small cell lung cancer (NSCLC)

AHFS therapeutic class: Antineoplastic Agents

Mechanism of action: Bispecific EGF receptor-directed and MET receptor-directed antibody

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for amivantamab-vmjw (Rybrevant®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Non-small cell lung cancer (NSCLC)

1. Disease is advanced, recurrent, or metastatic, **AND**
2. Presence of one of the following EGFR mutations:
    a. Presence of the EGFR exon 20 insertion mutation, or
    b. Exon 19 deletion, or
    c. Exon 21 L858R mutation, or
    d. S768I mutation, or
    e. L861Q mutation, or
    f. G719X mutation

    AND
3. Either of the following:
    a. Being used as a single agent, or
    b. Being used in combination with pemetrexed and carboplatin

Covered Doses

- *Less than 80 kg*: up to 1050 mg (3 vials) 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
- *Greater than or equal to 80 kg*: up to 1400 mg (4 vials) 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

Coverage Period
Indefinitely

ICD-10:

C33, C34.00-C34.02, C34.10-C34.12, C34.2, C34.30-C34.32, C34.80-C34.82, C34.90-C34.92, Z85.118

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for amivantamab-vmjw (Rybrevant®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 350 mg/7 mL (50 mg/mL) solution in a single-dose vial

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- National Comprehensive Cancer Network. Non-Small Cell Lung Cancer (Version 3.2022). Available at: www.nccn.org.
- Rybrevant® (amivantamab-vmjw) [Prescribing information]. Horsham, PA: Janssen Biotech, Inc.; 11/2022.

(7) Policy Update

Date of last revision: 1Q2024
Date of next review: 3Q2024
Changes from previous policy version:

- Section (2): Non-small cell lung cancer –
  - Expanded coverage to include use as first-line therapy in combination with pemetrexed and carboplatin
  - Expanded coverage of NSCLC to include EGFR exon 19 deletion, exon 21 L858R, S768I, L861Q, and G7719X mutations

Rationale: NCCN category 1 support

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee