**Medical Policy**

| **Rybrevant™** (amivantamab) | |
|---|---|
| **MEDICAL POLICY NUMBER** | Med_Clin_Ops_074 |
| **CURRENT VERSION EFFECTIVE DATE** | January 1, 2024 |
| **APPLICABLE PRODUCT AND MARKET** | *Individual Family Plan:* All Plans<br>*Small Group*: All Plans<br>*Medicare Advantage:* All Plans |

*Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.*

*If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.*

*Brand New Day/Central Health Medicare Plan medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Brand New Day/Central Health Medicare Plan medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Brand New Day/Central Health Medicare Plan does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies are updated based on changes in the evidence and healthcare coding and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG).*

## PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Rybrevant™ (amivantamab) therapy.

## POLICY/CRITERIA

## Prior Authorization and Medical Review is required.

Coverage for Rybrevant will be provided for 12 months and may be renewed.

1. Patient is 18 years of age or older; **AND**
2. Rybrevant is prescribed by, or in consultation with, an oncologist; **AND**
3. Patient has a diagnosis of 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*; **AND**

4. Patient's disease has progressed on or following prior treatment with a platinum based regimen.

**http://www.fda.gov/CompanionDiagnostics*

## LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

## BACKGROUND

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.

## DEFINITIONS

1. RYBREVANT (amivantamab-vmjw) injection, for intravenous use. Initial U.S. Approval: 2021
    a. RYBREVANT™ (amivantamab-vmjw) injection is a sterile, preservative-free, colorless to pale yellow solution for intravenous infusion. Each single-dose vial contains 350 mg/7 mL (50 mg/mL) RYBREVANT.
    b. Each vial is individually packed in a single carton. (NDC 57894-0501-01).

## CODING

| Applicable NDC Codes | |
|---|---|
| 57894-0501-01 | Rybrevant (amivantamab) 350 mg/7 mL solution, for intravenous infusion, in a single-use vial |

| Applicable Procedure Code | |
|---|---|
| J9061 | Injection, amivantamab-vmjw, 2 mg. Effective date: 01/01/2022 |

| Applicable ICD-10 Codes | |
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| C34.10 | Malignant neoplasm of upper lobe, unspecified bronchus or lung |
| C34.11 | Malignant neoplasm of upper lobe, right bronchus or lung |
| C34.12 | Malignant neoplasm of upper lobe, left bronchus or lung |
| C34.2 | Malignant neoplasm of middle lobe, bronchus or lung |
| C34.30 | Malignant neoplasm of lower lobe, unspecified bronchus or lung |
| C34.31 | Malignant neoplasm of lower lobe, right bronchus or lung |
| C34.32 | Malignant neoplasm of lower lobe, left bronchus or lung |

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| C34.80 | Malignant neoplasm of overlapping sites of unspecified bronchus and lung |
| C34.81 | Malignant neoplasm of overlapping sites of right bronchus and lung |
| C34.82 | Malignant neoplasm of overlapping sites of left bronchus and lung |
| C34.90 | Malignant neoplasm of unspecified part of unspecified bronchus or lung |
| C34.91 | Malignant neoplasm of unspecified part of right bronchus or lung |
| C34.92 | Malignant neoplasm of unspecified part of left bronchus or lung |

## EVIDENCE BASED REFERENCES

1. Product Information: RYBREVANT(TM) intravenous injection, amivantamab-vmjw intravenous injection. Janssen Biotech Inc (per FDA), Horsham, PA, 2021.

### POLICY HISTORY

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|---|---|
| Original Effective Date | July 19, 2021 |
| Revised Date | • Added j-code (J9061): Injection, amivantamab-vmjw, 2 mg Effective date : 01/01/2022<br>• February 28, 2023 – Annual review<br>• January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made) |

Approved by P&T Committee **2/28/23**