Utilization Review Policy 255

POLICY: Oncology (Injectable) – Rybrevant Utilization Management Medical Policy
- Rybrevant™ (amivantamab-vmjw intravenous infusion – Janssen Pharmaceuticals)

EFFECTIVE DATE: 09/01/2021
REVIEW DATE: 03/13/2024

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Rybrevant, a bispecific epidermal growth factor receptor (EGFR)-directed and mesenchymal epithelial transition (MET) receptor-directed antibody, is indicated for the treatment of locally advanced or metastatic **non-small cell lung cancer** (NSCLC) with EGFR exon 20 insertion mutations as detected by an FDA-approved test:[1]
- In combination with carboplatin and pemetrexed for the first-line treatment of adults.
- As a single agent, in adults whose disease has progressed on or after platinum-based chemotherapy.

Dosing

For first-line treatment:[1]
- For patients < 80 kg, the recommended dose is 1,400 mg administered by intravenous (IV) infusion once weekly for the first four doses, then 1,750 mg IV once every 3 weeks until disease progression or unacceptable adverse events (AEs).
- For patients ≥ 80 kg, the recommended dose is 1,750 mg for the first four doses followed by 2,100 mg IV once every 3 weeks until disease progression or unacceptable AEs.

For previously treated NSCLC:
- For patients < 80 kg, the recommended dose is 1,050 mg and for patients ≥ 80 kg the recommended dose is 1,400 mg. Rybrevant is administered by IV infusion once weekly for 4 weeks, then once every 2 weeks until disease progression or unacceptable AEs.

The initial dose is split and given on Days 1 and 2 of Week 1. Dose modifications are recommended for adverse events.

Guidelines

The National Comprehensive Cancer Network (NCCN) non-small cell lung cancer guidelines (version 2.2024 – February 9, 2024) recommend Rybrevant for the first-line treatment, in combination with carboplatin and pemetrexed and subsequent treatment, as a single agent, of EGFR exon 20 insertion mutation positive recurrent, advanced, or metastatic NSCLC.[2,3] In addition, Rybrevant is recommended for the subsequent treatment of recurrent, advanced, or metastatic NSCLC with EGFR exon 19 deletion, exon 21 *L858R*, or EGFR *S768I*, *L861Q* and/or *G719X* mutation, in combination with carboplatin and pemetrexed, following disease progression on Tagrisso® (osimertinib tablets).

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Rybrevant. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Rybrevant as well as the monitoring required

for adverse events and long-term efficacy, approval requires Rybrevant to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Rybrevant is recommended in those who meet the following criteria:

FDA-Approved Indication

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1. Non-Small Cell Lung Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

A) Patient is ≥ 18 years of age; AND

B) Patient has locally advanced or metastatic disease; AND

C) Patient meets ONE of the following (i or ii):

i. Patient has epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an approved test; OR

ii. Patient meets BOTH of the following (a and b):

a) Medication is used as subsequent therapy; AND

b) Patient has ONE of the following [(1), (2), or (3)]:

(1) EGFR exon 19 deletion; OR

(2) EGFR exon 21 L858R mutation; OR

(3) EGFR S768I, L861Q, and/or G719X mutation; AND

D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve one of the following dosing regimens (A or B):

A) First-line treatment:

a. Weight < 80 kg: Approve up to 1,400 mg administered by intravenous infusion once weekly for the first four doses, then approve up to 1,750 mg administered intravenously no more frequently than once every 3 weeks; OR
Note: The initial dose is divided and given on two consecutive days in the first week.

b. Weight ≥ 80 kg: Approve up to 1,750 mg administered by intravenous infusion once weekly for the first four doses, then approve up to 2,100 mg administered intravenously no more frequently than once every 3 weeks; OR
Note: The initial dose is divided and given on two consecutive days in the first week.

B) Subsequent treatment:

a. Weight < 80 kg: Approve up to 1,050 mg administered by intravenous infusion no more frequently than once weekly; OR
Note: The initial dose is divided and given on two consecutive days in the first week.

b. Weight ≥ 80 kg: Approve up to 1,400 mg administered by intravenous infusion no more frequently than once weekly.
Note: The initial dose is divided and given on two consecutive days in the first week.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Rybrevant is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Rybrevant intravenous infusion [prescribing information]. Horsham, PA: Janssen; March 2024.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed March 11, 2024. Search term; amivantamab.
3. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 2.2024 – February 9, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed March 11, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	06/14/2023
Early Annual Revision	**Non-Small Cell Lung Cancer:** Added requirement that the patient has locally advanced or metastatic disease. Added option for approval that the medication is used as subsequent therapy and the patient has epidermal growth factor (EGFR) exon 19 deletion, EGFR exon 21 *L858R* mutation, or EGFR *S768I*, *L861Q*, and/or *G719X* mutation. Added first-line dosing regimens to Dosing section.	03/13/2024