VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

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

REVIEW DATE: 06/15/2022

OVERVIEW

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

Dosing

For patients < 80 kg the recommended dose is 1,050 mg and for patients ≥ 80 kg the recommended dose is 1,400 mg.[1] Rybrevant is administered by intravenous infusion once weekly for 4 weeks, then once every 2 weeks until disease progression or unacceptable adverse events. 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 3.2022 – March 16, 2022) recommend Rybrevant for the subsequent treatment of EGFR exon 20 insertion mutation positive recurrent, advanced, or metastatic non-small cell lung cancer as a single agent.[2,3]

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

1. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has epidermal growth factor receptor exon 20 insertion mutations, as detected by an approved test; AND
   - **C)** The medication is used as subsequent therapy; 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)** 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; December 2021.
2. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 17, 2022. Search term; amivantamab.
3. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 17, 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	06/02/2021
Annual Revision	**Non-Small Cell Lung Cancer:** The requirement that the patient has progressed on or following platinum based chemotherapy was removed. The requirement that the medication is used as subsequent therapy was added.	06/15/2022