PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Rybrevant Prior Authorization 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.

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 prescription benefit coverage of Rybrevant. 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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

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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.

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