

STANDARD MEDICARE PART B MANAGEMENT

Rybrevant (amivantamab-vmjw)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

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.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions: Documentation of test results showing the presence of EGFR exon 20 insertion mutations.

III. CRITERIA FOR INITIAL APPROVAL

Non-small cell lung cancer (NSCLC)

Authorization of 12 months may be granted for treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, whose disease has progressed on or after platinum-based chemotherapy.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

1. The member is currently receiving therapy with Rybrevant
2. Rybrevant is being used to treat an indication enumerated in Section III
3. The member is receiving benefit from therapy. Benefit is defined as:
 - i. No evidence of unacceptable toxicity while on the current regimen and

Reference number(s)
4742-A

- ii. No evidence of disease progression while on the current regimen

V. REFERENCES

1. Rybrevant [package insert]. Horsham, PA: Janssen Biotech, Inc.; May 2021.