Reference number(s)
6610-A

SPECIALTY GUIDELINE MANAGEMENT

LAZCLUZE (lazertinib)

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.

A. FDA-Approved Indication
Lazcluze is indicated in combination with amivantamab for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test.

B. Compendial Use
Recurrent, advanced, or metastatic EGFR exon 19 deletion or exon 21 L858R mutation positive NSCLC in combination with lazertinib

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Test results showing the presence of EGFR exon 19 deletion or exon 21 L858R substitution mutations.

III. CRITERIA FOR INITIAL APPROVAL

Non-Small Cell Lung Cancer (NSCLC)
Authorization of 12 months may be granted for first-line treatment of recurrent, advanced, or metastatic NSCLC with EGFR exon 19 deletion or exon 21 L858R substitution mutations when used in combination with amivantamab (Rybrevant).

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity while on the current regimen.

V. REFERENCES

1. Lazcluze [package insert]. Horsham, PA: Janssen Biotech, Inc.; August 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed September 10, 2024.

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