

# Specialty Guideline Management

## Lazcluze

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lazcluze	lazertinib

### 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 Indications<sup>1</sup>

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.

#### Compendial Use<sup>2</sup>

Recurrent, advanced, or metastatic EGFR exon 19 deletion or exon 21 L858R mutation positive NSCLC in combination with amivantamab

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

## 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.

## Coverage Criteria

### Non-Small Cell Lung Cancer (NSCLC)<sup>1,2</sup>

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).

### Continuation of Therapy<sup>1,2</sup>

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

## 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