

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Lazcluze Prior Authorization Policy

- Lazcluze™ (lazertinib tablets – Janssen)

**REVIEW DATE:** 08/26/2024

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### OVERVIEW

Lazcluze, in combination with Rybrevant™ (amivantamab-vmjw infusion), is indicated for the first-line treatment of 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, in adults.<sup>1</sup>

### Guidelines

Lazcluze is not addressed in the National Comprehensive Cancer Network (NCCN) guidelines for NSCLC (version 8.2024 – August 23, 2024).<sup>2</sup> NCCN recommends Tagrisso® (osimertinib tablets) as the “Preferred” first-line treatment (category 1) for patients with *EGFR* exon 19 deletion or exon 21 L858R substitution mutations. Several other *EGFR* tyrosine kinase inhibitors with or without chemotherapy or bevacizumab are recommended under “Other Recommended” regimens (most are category 1).

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Lazcluze. All approvals are provided for the duration noted below.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Lazcluze 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 ALL of the following (A, B, C, D, and E):
    - A) Patient is  $\geq 18$  years of age; AND
    - B) Patient has locally advanced or metastatic disease; AND
    - C) Patient has epidermal growth factor receptor (*EGFR*) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an approved test; AND
    - D) The medication is used in combination with Rybrevant™ (amivantamab-vmjw infusion); AND
    - E) The medication will be used as first-line treatment.
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**CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of Lazcluze 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. Lazcluze™ tablets [prescribing information]. Horsham, PA: Janssen; August 2024.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 8.2024 – August 23, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 26, 2024.

**HISTORY**

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/26/2024