

Applicable Drugs: Lazcluze (lazertinib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/24/2025

Date Last Reviewed / Revised: 2/19/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met.)

- I. Documentation of the following FDA-approved diagnoses (A) AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication

A. Non-small cell lung cancer

1. Documentation of locally advanced or metastatic disease that is not curable.
2. Documentation of either epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test.
3. Used for first-line treatment in combination with Rybrevant (amivantamab).
4. Documented clinical rationale for not using Tagrisso (osimertinib).

Other Uses With Supportive Evidence

B. Non-small cell lung cancer, subsequent therapy

- II. Minimum age requirement: 18 years old.
- III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantity limit:
 - 240 mg tablets: 30 tablets per 30 days
 - 80 mg tablets: 60 tablets per 30 days

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

1. Lazcluze. Prescribing Information. Janssen Biotech, Inc. 2025. Accessed February 19, 2026. www.accessdata.fda.gov/drugsatfda_docs/label/2024/219008s000lbletdt.pdf
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer. Version 3.2026. Updated December 24, 2025. Accessed February 19, 2026.
3. Cho BC, Lu S, Felip, E, et al. Amivantamab plus lazertinib in previously untreated EGFR-mutated advanced NSCLC. *N Engl J Med*. 2024;391:1486-98. Doi: 10.1056/NEJMoa2403614

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.