Lazcluze™ (lazertinib)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
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 Uses
Recurrent, advanced, or metastatic EGFR exon 19 deletion or exon 21 L858R mutation positive NSCLC

POLICY

Required 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.

Criteria for Initial Approval
Non-Small Cell Lung Cancer (NSCLC)
Authorization of 12 months may be granted for 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), or amivantamab and hyaluronidase-lpuj (Rybrevant Faspro).

Continuation of Therapy

Non-Small Cell Lung Cancer (NSCLC)
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Criteria for Initial Approval Section when there is no evidence of unacceptable toxicity while on the current regimen.

Other
Lazcluze (lazertinib) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Lazcluze (lazertinib) 80 mg tablet	60 tablets per 30 days	240 mg orally once daily Dose may be reduced to 160 mg once daily, and subsequently to 80 mg once daily if adverse reactions occur
Lazcluze (lazertinib) 240 mg tablet	30 tablets per 30 days	

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

Lazcluze [package insert]. Horsham, PA: Janssen Biotech, Inc.; August 2024.

The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 27, 2026.

POLICY HISTORY

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