BlueCross BlueShield
Federal Employee Program

LAZCLUZE
(lazertinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Lazcluze (lazertinib) is a kinase inhibitor of epidermal growth factor receptor (EGFR) that inhibits EGFR exon 19 deletions and exon 21 L858R substitution mutations at lower concentrations than wild-type EGFR. In human non-small cell lung cancer (NSCLC) cells and mouse xenograft models of EGFR exon 19 deletions or EGFR L858R substitution mutations, Lazcluze demonstrated anti-tumor activity and treatment in combination with amivantamab increased in vivo anti-tumor activity compared to either agent alone (1).

Regulatory Status

FDA-approved indication: Lazcluze is a kinase inhibitor 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 (1).

Lazcluze has warnings regarding the following: venous thromboembolic events (VTE), interstitial lung disease (ILD)/pneumonitis, dermatologic adverse reactions, ocular adverse reactions, and embryo-fetal toxicity. When initiating treatment with Lazcluze in combination with amivantamab, administer anticoagulant prophylaxis to prevent VTE events for the first four months of treatment (1).

Lazcluze can cause fetal harm when administered in pregnant women. Females of reproductive potential should be advised to use effective contraception during treatment with Lazcluze and for 3 weeks after the last dose. Males with female partners of reproductive potential should be advised to use effective contraception during treatment with Lazcluze and for 3 weeks after the last dose (1).

The safety and effectiveness of Lazcluze in pediatric patients less than 18 years of age have not been established (1).

Summary

Lazcluze (lazertinib) is a kinase inhibitor of epidermal growth factor receptor (EGFR). It is indicated

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for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations. Lazcluze has warnings regarding the following: venous thromboembolic events (VTE), interstitial lung disease (ILD)/pneumonitis, dermatologic adverse reactions, ocular adverse reactions, and embryo-fetal toxicity. The safety and effectiveness of Lazcluze in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Lazcluze while maintaining optimal therapeutic outcomes.

References

1. Lazcluze [package insert]. Horsham, PA: Janssen Biotech, Inc.; August 2024.
2. NCCN Drugs & Biologics Compendium® Lazertinib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 15, 2025.