PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Lazcluze Prior Authorization Policy
- Lazcluze™ (lazertinib tablets – Janssen)

REVIEW DATE: 08/26/2024

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.[1]

Guidelines

Lazcluze is not addressed in the National Comprehensive Cancer Network (NCCN) guidelines for NSCLC (version 8.2024 – August 23, 2024).[2] 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 ≥ 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.

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.