PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 08/26/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

- **Lazcluze™ (lazertinib tablets - Janssen)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

- **Lazcluze™ (lazertinib tablets - Janssen)**

is(are) considered experimental, investigational, or unproven for ANY other uses (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