UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2024 P 1459-1 |
| Program | Prior Authorization/Notification |
| Medication | Lazcluze™ (lazertinib) |
| P&T Approval Date | 10/2024 |
| Effective Date | 2/1/2025 |

**1. Background:**

Lazcluze (lazertinib) is a kinase inhibitor indicated in combination with Rybrevant (amivantamab-vmjw) 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.[1] The National Cancer Comprehensive Network (NCCN) also recommends the use of Lazcluze in combination with Rybrevant for EGFR exon 19 deletion or exon 21 L858R recurrent NSCLC as continuation of therapy following disease progression on Rybrevant and Lazcluze for asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited progression.[2]

**Coverage Information:**
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

**2. Coverage Criteria[a]:**

**A. <u>Patients less than 19 years of age</u>**

1. **Lazcluze** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   **Authorization will be issued for 12 months.**

**B. <u>Non-Small Cell Lung Cancer (NSCLC)</u>**

1. **<u>Initial Authorization</u>**

   a. **Lazcluze** will be approved based on **<u>all</u>** of the following criteria:

      (1) Diagnosis of non-small cell lung cancer (NSCLC)

      **-AND-**

      (2) Disease is **one** of the following:

(a) Recurrent
(b) Advanced
(c) Metastatic

**-AND-**

(3) Disease is positive for **one** of the following:

(a) Epidermal growth factor receptor (EGFR) exon 19 deletion
(b) EGFR exon 21 L858R mutation

**AND-**

(4) Used in combination with Rybrevant (amivantamab-vmjw)

**Authorization will be issued for 12 months.**

2. **Reauthorization**

a. **Lazcluze** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Lazcluze therapy

**Authorization will be issued for 12 months.**

**C. NCCN Recommended Regimens**

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

**Authorization will be issued for 12 months.**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**

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

2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org. Accessed September 12, 2024.

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|---|---|
| **Change Control** | |
| 10/2024 | New program. |