

# SPECIALTY GUIDELINE MANAGEMENT

## ALECENSA (alectinib)

### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

Alecensa is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

B. Compendial Uses

1. Recurrent or advanced NSCLC, ALK rearrangement-positive as a single agent
2. Brain metastases from ALK rearrangement-positive NSCLC as a single agent
3. Relapsed/refractory ALK+ anaplastic large cell lymphoma as a single agent

All other indications are considered experimental/investigational and not medically necessary.

#### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: ALK mutation status

#### III. CRITERIA FOR INITIAL APPROVAL

A. **Non-Small Cell Lung Cancer (NSCLC)**

Authorization of 12 months may be granted for treatment of recurrent, advanced or metastatic ALK-positive NSCLC (including brain metastases from NSCLC) as a single agent.

B. **Anaplastic Large Cell Lymphoma (ALCL)**

Authorization of 12 months may be granted for treatment of relapsed/refractory ALK-positive ALCL as a single agent.

#### IV. CONTINUATION OF THERAPY

A. **Non-Small Cell Lung Cancer (NSCLC)**

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity while on the current regimen.

B. **Anaplastic Large Cell Lymphoma (ALCL)**

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

<b>Reference number(s)</b>
2150-A

## V. REFERENCES

1. Alecensa [package insert]. South San Francisco, CA: Genentech USA, Inc.; September 2021.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed March 9, 2022.