

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.

Reference number(s)
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.