| Reference number(s) |
|---|
| 2150-A |

# 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
1. Alecensa is indicated as adjuvant treatment in adult patients following tumor resection of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) (tumors ≥ 4 cm or node positive), as detected by an FDA-approved test.
2. 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
2. Brain metastases from ALK rearrangement-positive NSCLC
3. ALK+ anaplastic large cell lymphoma
4. ALK+ large B-cell lymphoma
5. Inflammatory myofibroblastic tumor (IMT) with ALK translocation
6. Erdheim-Chester Disease with ALK fusion

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)**
1. 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.
2. Authorization of 12 months may be granted for the adjuvant treatment of ALK-positive NSCLC (tumors ≥ 4 cm or node positive) following complete tumor resection as a single agent.

**B. Anaplastic Large Cell Lymphoma (ALCL)**
Authorization of 12 months may be granted for initial palliative therapy or treatment of relapsed/refractory ALK-positive ALCL as a single agent.

**C. Large B-Cell Lymphoma (LBCL)**

Authorization of 12 months may be granted for treatment of relapsed/refractory ALK-positive large B-cell lymphoma.

**D. Inflammatory Myofibroblastic Tumor (IMT)**
Authorization of 12 months may be granted for treatment of ALK-positive IMT as a single agent when either of the following criteria is met:
1. The member has uterine sarcoma and the disease is advanced, recurrent, metastatic, or inoperable
2. The member has a soft tissue sarcoma (not including uterine sarcoma)

**E. Erdheim-Chester Disease (ECD)**
Authorization of 12 months may be granted for treatment of symptomatic or relapsed/refractory ALK-positive Erdheim-Chester disease as a single agent.

## IV. CONTINUATION OF THERAPY

**A. Non-Small Cell Lung Cancer (NSCLC)**
1. Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for recurrent, advanced, or metastatic NSCLC when there is no evidence of unacceptable toxicity while on the current regimen.
2. Authorization of 12 months (up to a maximum duration of 2 years) may be granted for continued treatment in members requesting reauthorization for adjuvant treatment of NSCLC when there is no evidence of unacceptable toxicity or disease recurrence while on the current regimen.

**B. All Other Indications**
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for all other indications listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

## V. REFERENCES

1. Alecensa [package insert]. South San Francisco, CA: Genentech USA, Inc.; September 2021.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 14, 2024.
3. NCCN Clinical Practice Guidelines in Oncology® Non-Small Cell Lung Cancer (Version 5.2024). © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 23, 2024.