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
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. Uterine Sarcoma - 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)
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 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. Uterine Inflammatory Myofibroblastic Tumor (IMT)
Authorization of 12 months may be granted for treatment of uterine inflammatory myofibroblastic tumor (IMT) when all of the following criteria are met:

1. The disease is advanced, recurrent, metastatic, or inoperable
2. The disease is ALK-positive
3. The requested medication will be used as a single agent

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)
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. 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® © 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed February 27, 2023.