

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 as a single agent
2. Brain metastases from ALK rearrangement-positive NSCLC as a single agent

All other indications are considered experimental/investigational and are 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

##### **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.

#### IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III who have not experienced an unacceptable toxicity.

#### V. REFERENCES

1. Alecensa [package insert]. South San Francisco, CA: Genentech USA, Inc.; June 2018.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed February 20, 2020.