

Clinical Pharmacy Program Guidelines for Alecensa

Program	Prior Authorization
Medication	Alecensa [®] (alectinib)
Issue Date	3/2016
Pharmacy and Therapeutics Approval Date	8/2017
Effective Date	10/2017

1. Background:

Alecensa[®] (alectinib) is a kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to Xalkori[®] (crizotinib).¹ The National Cancer Comprehensive Network (NCCN) also recommends Alecensa as first-line therapy for recurrent or metastatic ALK-positive NSCLC.

2. Coverage Criteria:

<p>A. <u>Non-Small Cell Lung Cancer (NSCLC)</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Alecensa will be approved based on all of the following criteria:</p> <p>(1) Diagnosis of non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;">-AND-</p> <p>(2) Disease is one of the following:</p> <p>(a) Metastatic (b) Recurrent</p> <p style="text-align: center;">-AND-</p> <p>(3) Tumor is anaplastic lymphoma kinase (ALK)-positive</p> <p>Authorization will be issued for 12 months.</p> <p>2. <u>Reauthorization</u></p>

a. **Alecensa** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Alecensa therapy

Authorization will be issued for 12 months.

3. References:

1. Alecensa [package insert]. South San Francisco, CA: Genentech USA, Inc.; November 2016.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed July 7, 2017.

Program	Prior Authorization –Alecensa (alectinib)
Change Control	
Date	Change
3/2016	New program
8/2016	Updated clinical criteria to align with Employer and Individual except less than 19 criteria
3/2017	Annual review. Updated references and policy template.
8/2017	Updated background and criteria to include NCCN recommendation of first line use in ALK-positive metastatic or recurrent NSCLC.