



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2018 P 1182-4
Program	Prior Authorization/Notification
Medication	Alecensa <sup>®</sup> (alectinib)
P&T Approval Date	5/2016, 3/2017, 8/2017, 8/2018
Effective Date	11/1/2018; Oxford only: 11/1/2018

**1. Background:**

Alecensa<sup>®</sup> (alectinib) is a kinase inhibitor 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.

**Coverage Information:**

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

**2. Coverage Criteria:**

**A. Patients less than 19 years of age**

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

- a. Patient is less than 19 years of age

**Authorization will be issued for 12 months.**

**B. Non-Small Cell Lung Cancer (NSCLC)**

1. **Initial Authorization**

a. **Alecensa** will be approved based on **all** of the following criteria:

- (1) Diagnosis of non-small cell lung cancer (NSCLC)

**-AND-**

(2) Disease is **one** of the following:

- (a) Metastatic

(b) Recurrent

**-AND-**

(3) Tumor is anaplastic lymphoma kinase (ALK)-positive

**Authorization will be issued for 12 months.**

**2. Reauthorization**

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. Additional Clinical Rules:**

- Supply limits may be in place.

**4. References:**

1. Alecensa [package insert]. South San Francisco, CA: Genentech USA, Inc.; June 2018.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at [http://www.nccn.org/professionals/drug\\_compendium/content/contents.asp](http://www.nccn.org/professionals/drug_compendium/content/contents.asp). Accessed June 18, 2018.

Program	Prior Authorization/Notification - Alecensa (alectinib)
<b>Change Control</b>	
5/2016	New criteria.
3/2017	Annual review, changed member to patient, with no change to criteria. Updated references.
8/2017	Updated background and criteria to include NCCN recommendation of first line use in ALK-positive metastatic or recurrent NSCLC. Updated criteria formatting to align with other ALK NSCLC agents.
8/2018	Updated background to include updated labeled indication for initial therapy in metastatic ALK-positive NSCLC. Updated references.