UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Alecensa

Program	Prior Authorization
Medication	Alecensa® (alectinib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, - CHIP, Rhode Island, South Carolina
Issue Date	3/2016
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

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) as detected by an FDA-approved test.

2. Coverage Criteria:

A. 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.

B. NCCN Recommended Regimens

1. Initial Authorization

a. **Alecensa** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Alecensa therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- 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. Accessed August 6, 2020.

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.
8/2018	Updated background to include updated labeled indication for initial therapy in metastatic ALK-positive NSCLC. Added NCCN recommended regimen criteria. Updated references.
9/2019	Annual review with no changes to coverage criteria. Updated references.
9/2020	Annual review with no changes to clinical coverage criteria. Updated reference. Added Additional Clinical Rules section.