UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1182-11
Program	Prior Authorization/Notification
Medication	Alecensa® (alectinib)
P&T Approval Date	5/2016, 3/2017, 8/2017, 8/2018, 9/2019, 9/2020, 8/2021, 8/2022, 8/2023, 6/2024, 6/2025
Effective Date	9/1/2025

1. Background:

Alecensa (alectinib) is a kinase inhibitor indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test and for adjuvant treatment in adult patients following tumor resection of ALK-positive NSCLC (tumors ≥ 4 cm or node positive) as detected by an FDA-approved test. The NCCN also recommends Alecensa for ALK-fusion targeted relapsed/refractory, symptomatic Erdheim-Chester Disease, as second-line or initial palliative intent therapy and subsequent therapy for relapsed/refractory ALK+ anaplastic large cell lymphoma (ALCL), relapsed or refractory ALK-positive large B-Cell lymphoma, ALK-positive metastatic brain cancer from NSCLC, ALK-rearrangement positive pediatric diffuse high-grade glioma, and inflammatory myofibroblastic tumors with ALK translocation.

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]:

A. <u>Patients less than 19 years of age</u>

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. <u>Non-Small Cell Lung Cancer (NSCLC)</u>

1. **<u>Initial Authorization</u>**

   a. **Alecensa** will be approved based on **<u>all</u>** of the following criteria:

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

© 2025 UnitedHealthcare Services, Inc.

-AND-

(2) Disease is anaplastic lymphoma kinase (ALK)-positive

-AND-

(3) **One** of the following:

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

i. Recurrent
ii. Advanced
iii. Metastatic

-OR-

(b) Used as adjuvant treatment following tumor resection

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.

C. Histiocytic Neoplasms

1. **Initial Authorization**

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

(1) Diagnosis of symptomatic Erdheim-Chester Disease

-AND-

(2) Used as targeted therapy ALK-fusion

-AND-

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

(a) Relapsed
(b) Refractory

Authorization will be issued for 12 months.

© 2025 UnitedHealthcare Services, Inc.

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.

D. T-Cell Lymphomas

1. **Initial Authorization**

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

(1) Diagnosis of anaplastic large cell lymphoma (ALCL)

-AND-

(2) Used as initial palliative intent therapy or second-line and subsequent therapy

-AND-

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

(a) Relapsed
(b) Refractory

-AND-

(4) 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.

E. B-Cell Lymphomas

1. **Initial Authorization**

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

(1) Diagnosis of large B-Cell lymphoma

-AND-

© 2025 UnitedHealthcare Services, Inc.

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

(a) Relapsed
(b) Refractory

-AND-

(3) 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.

F. Central Nervous System (CNS) Cancers / Pediatric Central Nervous System Cancers - Pediatric Diffuse

1. **Initial Authorization**

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

(1) **One** of the following:
(a) Diagnosis of metastatic brain cancer from NSCLC
(b) Diagnosis of pediatric diffuse high-grade glioma

-AND-

(2) 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.

G. Soft Tissue Sarcoma/Uterine Neoplasms

1. **Initial Authorization**

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

© 2025 UnitedHealthcare Services, Inc.

(1) Diagnosis of inflammatory myofibroblastic tumor (IMT)

-AND-

(2) Presence of ALK translocation

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.

H. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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.; April 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/ . Accessed May 9, 2025.

© 2025 UnitedHealthcare Services, Inc.

Program	Prior Authorization/Notification - Alecensa (alectinib)
Change Control	
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.
9/2019	Annual review with no changes to clinical coverage criteria. Updated reference. Added general NCCN recommended review criteria.
9/2020	Annual review with no changes to clinical coverage criteria. Updated reference.
8/2021	Annual review. Added advanced disease to criteria. Updated references.
8/2022	Annual review. Updated background and references. Added criteria per NCCN recommendations for histiocytic neoplasms and t-cell lymphomas. Added state mandate footnote.
8/2023	Annual review. Updated histiocytic neoplasm and T-Cell lymphoma formatting with no change to clinical criteria. Added criteria for B-Cell lymphoma, CNS cancer and IMT tumors per NCCN guidelines.
6/2024	Added criteria for adjuvant treatment following tumor resection of ALK-positive NSCLC per FDA label. Updated references.
6/2025	Annual review. Added criteria for pediatric diffuse high-grade gliomas per NCCN guidelines. Updated background and references.

© 2025 UnitedHealthcare Services, Inc.