

PHARMACY COVERAGE GUIDELINE

ALECENSA® (alectinib) oral Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
 - This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
 - Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
 - The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
 - The “Description” section describes the Service.
 - The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
 - The “Resources” section lists the information and materials we considered in developing this PCG
 - **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
 - Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.
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Medical Necessity Requirements for ALECENSA (alectinib)

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by an Oncologist or in consultation with an Oncologist

Indication

- **ONE** of the following:
 - Anaplastic lymphoma kinase (ALK) positive metastatic non small cell lung cancer (NSCLC) as detected by a United States Food and Drug Administration (FDA) approved test

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- Adjuvant treatment following tumor resection of ALK positive NSCLC (tumors greater than 4 cm or node positive) as detected by an FDA approved test
- Other oncologic direct treatment use listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

Age Requirement

- 18 years or older

Baseline Clinical Evaluation

- Presence of ALK positivity in tumor tissue or plasma specimens
- Liver enzyme tests: alanine transaminase (ALT), aspartate transaminase (AST), and total bilirubin
- Negative pregnancy test in a woman of childbearing potential
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 2

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Documentation Requirements

- A completed request form must be submitted including:
 - Chart notes
 - Lab results (ALK positivity, liver enzymes, pregnancy test, ECOG status)
 - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year
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Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification

- Continues to be seen by an Oncologist or is in consultation with an Oncologist

Clinical Response

- Positive clinical response defined as no evidence of disease progression or unacceptable toxicity

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

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Safety

- No significant adverse drug effects such as:
 - Hepatotoxicity
 - Interstitial lung disease/Pneumonitis
 - Renal impairment
 - Bradycardia (life threatening consequences, urgent intervention needed)
 - Hemolytic anemia

Additional Requirements

- Requested dose is at least 300mg twice daily

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values that confirm safe use (liver enzymes, ECOG status, etc.)

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year
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Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications
 2. Off-Label Use of Cancer Medications
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Description:

Alecensa (alectinib) is a tyrosine kinase inhibitor that is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC). Alecensa (alectinib) is also indicated for adjuvant treatment in adult patients following tumor resection of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) (tumors \geq 4 cm or node positive).

Alectinib binds to and inhibits ALK kinase. Inhibition leads to disruption of ALK-mediated signaling and eventually inhibits tumor cell growth in ALK-overexpressing tumor cells. ALK belongs to the insulin receptor superfamily and plays an important role in nervous system development. ALK dysregulation and gene rearrangements are associated with a series of tumors.

Lung cancer:

- Lung cancer is the second most common cancer in the United States and it is the leading cause of cancer-related mortality

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- There are two main types of lung cancer:
 - Small cell lung cancer (SCLC)
 - SCLC is also known as “oat-cell” cancer because the cells look like oats under the microscope
 - Non-small cell lung cancer (NSCLC)
 - NSCLC is the most common type of lung cancer and is seen in 85-90% of lung cancers
 - NSCLC can be either squamous or non-squamous type
 - Classification:
 - Adenocarcinoma
 - Adenosquamous carcinoma
 - Large-cell undifferentiated carcinoma
 - Sarcomatoid carcinoma which includes pleomorphic carcinoma, carcinosarcoma, and pulmonary blastoma
 - Squamous cell carcinoma
 - Squamous (epidermoid) cells are thin, flat cells that look like fish scales
 - Squamous cells are seen in the tissues that line the larger airways
 - Non-squamous cancers usually begin in more distal airway
- Distribution of various NSCLC types:
 - About 40% of lung cancers are adenocarcinomas
 - About 25-30% of lung cancers are squamous cell carcinomas
 - About 10-15% of lung cancers are large cell undifferentiated carcinomas
- Brain metastases are a frequent complication of NSCLC, with 25-40% of patients developing brain metastases during the course of the disease
 - Many patients with brain metastases are not eligible for radiation therapy due to poor performance status
- An estimated 2-7% NSCLC are found to have ALK gene rearrangements and 15% of NSCLC cases have epidermal growth factor receptor (EGFR) mutations
 - ALK rearrangements and sensitizing EGFR mutations are generally mutually exclusive
 - Central nervous system progression is common with ALK gene rearrangements and accounts for significant morbidity and mortality among these patients
 - Individuals who are relatively young, never or light smokers with adenocarcinoma are most likely to have ALK gene rearrangements

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
[MedWatch Forms for FDA Safety Reporting | FDA](#)

Eastern Co-operative Oncology Group (ECOG) Performance Status:

Grade	ECOG description
0	Fully active, able to carry on all pre-disease performance without restriction

ORIGINAL EFFECTIVE DATE: 01/21/2016 | ARCHIVE DATE: | LAST REVIEW DATE: 02/19/2026 | LAST CRITERIA REVISION DATE: 02/20/2025

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1	Restricted in physical strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all self-care but unable to carry out any work activities, up and about more than 50% of waking hours
3	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
4	Completely disabled, cannot carry on any self-care, totally confined to bed or chair
5	Dead
Oken, MM, Creech, RH, Tormey, DC, et al.: Toxicity and Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982	

NCCN recommendation definitions:

Category 1:

Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2A:

Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2B:

Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.

Category 3:

Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate

Resources:

Alecensa (alectinib) product information, revised by Genentech, Inc. 04-2024. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed November 10, 2025.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Non-Small Cell Lung Cancer Version 3.2026 – Updated December 24, 2025. Available at <https://www.nccn.org>. Accessed December 30, 2025.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.