



5.21.075

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2025
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	January 15, 2016
<b>Subject:</b>	Alecensa	<b>Page:</b>	1 of 5

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**Last Review Date:** March 7, 2025

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## Alecensa

### Description

#### Alecensa (alectinib)

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#### Background

Alecensa (alectinib) is an oral medication indicated for the treatment of patients with non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive. Alecensa is an inhibitor of receptor tyrosine kinases including ALK and RET (rearranged during transfection). Translocations can affect the ALK gene resulting in the expression of oncogenic fusion proteins. The formation of ALK fusion proteins results in activation and dysregulation of the gene's expression and signaling which can contribute to increased cell proliferation and survival in tumors expressing these proteins. The administration of Alecensa in tumors carrying ALK fusions may result in antitumor activity and prolonged survival. Treatment with Alecensa should continue until disease progression or unacceptable toxicity (1).

#### Regulatory Status

FDA-approved indications: Alecensa is a kinase inhibitor indicated for (1):

- 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) as detected by an FDA-approved test.
- treatment of patients with ALK-positive metastatic NSCLC as detected by an FDA-approved test.

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2025
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	January 15, 2016
<b>Subject:</b>	Alecensa	<b>Page:</b>	2 of 5

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Liver function tests should be monitored every 2 weeks during the first 3 months of treatment, and then once a month and as clinically indicated. In case of severe ALT, AST, or bilirubin elevations, withhold, then reduce dose, or permanently discontinue Alecensa (1).

The safety of Alecensa in patients with severe renal impairment (creatinine clearance (CrCl) less than 30 mL/min) or end-stage renal disease has not been studied (1).

The safety and effectiveness of Alecensa in pediatric patients have not been established (1).

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## Related policies

Alunbrig, Lorbrena, Xalkori, Zykadia

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Alecensa may be considered **medically necessary** if the conditions indicated below are met.

Alecensa may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age and older

### Diagnoses

Patient must have **ONE** of the following:

1. Metastatic non-small cell lung cancer (NSCLC)
2. Adjuvant treatment of non-small cell lung cancer (NSCLC) following tumor resection
  - a. Tumors  $\geq 4$  cm **OR** node positive

**AND ALL** of the following:

1. Anaplastic lymphoma kinase (ALK)-positive as determined by FDA-approved test
2. **NO** severe renal impairment (CrCl less than 30 mL/min) or end stage renal

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<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	January 15, 2016
<b>Subject:</b>	Alecensa	<b>Page:</b>	3 of 5

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- disease
3. Prescriber agrees to monitor AST, ALT, and total bilirubin

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## Prior – Approval *Renewal* Requirements

**Age** 18 years of age and older

### Diagnoses

Patient must have **ONE** of the following:

1. Metastatic non-small cell lung cancer (NSCLC)
2. Adjuvant treatment of non-small cell lung cancer (NSCLC) following tumor resection

**AND ALL** of the following:

1. **NO** disease progression or unacceptable toxicity
2. **NO** severe renal impairment (CrCl less than 30 mL/min) or end stage renal disease
3. Prescriber agrees to monitor AST, ALT, and total bilirubin

### Policy Guidelines

## Pre - PA Allowance

None

## Prior - Approval Limits

**Quantity** 1,200 mg per day

**Duration** 12 months

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## Prior – Approval *Renewal* Limits

**Quantity** 1,200 mg per day

**Duration** 12 months

\*Adjuvant treatment of NSCLC following tumor resection is limited to **ONE** renewal **ONLY**

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2025
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	January 15, 2016
<b>Subject:</b>	Alecensa	<b>Page:</b>	4 of 5

## Rationale

### Summary

Alecensa (alectinib) is a kinase inhibitor indicated for the treatment of patients with non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive. The safety of Alecensa in patients with severe renal impairment (creatinine clearance less than 30 mL/min) or end-stage renal disease has not been studied. The safety and effectiveness of Alecensa in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Alecensa while maintaining optimal therapeutic outcomes.

### References

1. Alecensa [package insert]. South San Francisco, CA: Genentech USA, Inc.; April 2024.
2. NCCN Drugs & Biologics Compendium® Alectinib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 14, 2025.

## Policy History

Date	Action
January 2016	Addition to PA
March 2016	Annual review Policy number changed from 5.04.75 to 5.21.75
June 2016	Annual editorial review
June 2017	Annual editorial review and reference update
September 2017	Annual Review Addition of quantity limits
November 2017	Removal of the requirement of presence of disease progression on or intolerant to Xalkori (crizotinib) Addition of “as determined by FDA-approved test” to anaplastic lymphoma kinase (ALK)-positive
March 2018	Annual review
March 2019	Annual editorial review and reference update. Changed requirement from “no moderate to severe hepatic impairment” to “prescriber agrees to monitor AST, ALT, and total bilirubin”
June 2020	Annual review
March 2021	Annual editorial review and reference update
March 2022	Annual review and reference update
March 2023	Annual review and reference update. Changed policy number to 5.21.075

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2025
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	January 15, 2016
<b>Subject:</b>	Alecensa	<b>Page:</b>	5 of 5

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March 2024	Annual review and reference update
May 2024	Per PI update, added indication of adjuvant treatment of NSCLC following tumor resection
June 2024	Annual review and reference update
December 2024	Annual review and reference update
March 2025	Annual review and reference update

## [Keywords](#)

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.**