



5.21.75

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Antineoplastic Agents	Original Policy Date:	January 15, 2016
Subject:	Alecensa	Page:	1 of 4

Last Review Date: March 12, 2021

Alecensa

Description

Alecensa (alectinib)

Background

Alecensa (alectinib) is an oral medication indicated for the treatment of patients with metastatic 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. 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 indication: Alecensa is a kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test (1).

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).

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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. The safety of Alecensa in patients with moderate to severe hepatic impairment has not been studied (1).

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

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** in patients age 18 years or age or older for ALK-Positive Metastatic Non-Small Cell Lung Cancer (NSCLC) and if the conditions indicated below are met.

Alecensa may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

The patient must have the following:

Metastatic non-small cell lung cancer (NSCLC)

- a. Anaplastic lymphoma kinase (ALK)-positive as determined by FDA-approved test

AND ALL of the following:

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

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Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

The patient must have the following:

Metastatic non-small cell lung cancer (NSCLC)

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 720 capsules per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Alecensa (alectinib) is a kinase inhibitor indicated for the treatment of patients with metastatic 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), end-stage renal disease or moderate to severe hepatic impairment has not been studied. The safety and effectiveness of Alecensa in pediatric patients have not been established (1).

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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.; January 2021.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.