BlueCross BlueShield Federal Employee Program

ALECENSA
(alectinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

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 ≥ 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.

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).

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.