

# Alecensa (alectinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

  

Medications	Quantity Limit
Alecensa (alectinib)	May be subject to quantity limit

## APPROVAL CRITERIA

Requests for Alecensa (alectinib) may be approved if the following criteria are met:

I. Individual has recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC);

**AND**

II. Disease is anaplastic lymphoma kinase (ALK)-positive;

**OR**

III. Individual has progressed on or is intolerant to Xalkori (crizotinib) (NCCN 2A);

**OR**

IV. Individual has a diagnosis of metastatic NSCLC with brain metastases (NCCN 2A);

**AND**

V. Individual has a primary diagnosis of ALK-positive NSCLC;

**OR**

VI. Individual has a diagnosis of anaplastic large cell lymphoma (ALCL) (NCCN 2A); **AND**

VII. Disease is anaplastic lymphoma kinase (ALK)-positive; **AND**

VIII. Individual is using for second-line or palliative therapy;

**OR**

IX. Individual has a diagnosis of Erdheim-Chester Disease (ECD) (NCCN 2A); **AND**

X. Disease is anaplastic lymphoma kinase (ALK)-positive; **AND**

XI. Disease is symptomatic, relapsed, or refractory; **AND**

XII. Individual is using as single agent therapy;

**OR**

XIII. Individual has a diagnosis of Uterine Sarcoma; **AND**

XIV. Disease is anaplastic lymphoma kinase (ALK)-positive (NCCN 2A); **AND**

XV. Individual is using as a single-agent treatment;

**OR**

XVI. Individual has a diagnosis of Soft Tissue Sarcoma; **AND**

XVII. Disease is anaplastic lymphoma kinase (ALK)-positive (NCCN 2A); **AND**

XVIII. Individual is using as a single-agent treatment.

## **Key References:**

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6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
7. Reed DR, Hall RD, Gentzler RD, Volodin L, Douvas MG, Portell CA. Treatment of Refractory ALK Rearranged Anaplastic Large Cell Lymphoma With Alectinib. *Clin Lymphoma Myeloma Leuk*. 2019;19(6):e247-e250. doi:10.1016/j.clml.2019.03.001
8. Tomlinson SB, Sandwell S, Chuang ST, Johnson MD, Vates GE, Reagan PM. Central nervous system relapse of systemic ALK-rearranged anaplastic large cell lymphoma treated with alectinib. *Leuk Res*. 2019;83:106164. doi:10.1016/j.leukres.2019.05.014
9. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on September 9, 2023.
10. B-Cell Lymphomas. V5.2023. Revised July 28, 2023.
11. Central Nervous System Cancers. V1.2023. Revised March 24, 2023.
12. Non-Small Cell Lung Cancer. V3.2023. Revised April 13, 2023.
13. Histiocytic Neoplasms. V1.2023. Revised August 11, 2023.
  - a. Soft Tissue Sarcoma. V2.2023. Revised April 25, 2023.
  - b. T-Cell Lymphomas. V1.2023. Revised January 5, 2023.
  - c. Uterine Neoplasms. V2.2023. Revised April 28, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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