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 is under 19 years of age;

OR

II. Individual has a diagnosis of non-small cell lung cancer (NSCLC) (Label, NCCN 1, 2A); **AND**
III. Disease is anaplastic lymphoma kinase (ALK)-positive;

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, subsequent therapy, or palliative therapy;

OR

IX. Individual has a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) (NCCN 2A); **AND**
X. Disease is anaplastic lymphoma kinase (ALK)-positive;

OR

XI. Individual has a diagnosis of Erdheim-Chester Disease (ECD) (NCCN 2A); **AND**
XII. Disease is anaplastic lymphoma kinase (ALK)-positive; **AND**
XIII. Disease is symptomatic, relapsed, or refractory; **AND**
XIV. Individual is using as single agent therapy;

OR

XV. Individual has a diagnosis of uterine sarcoma; **AND**

XVI. Individual has an inflammatory myofibroblastic tumor (IMT); **AND**
XVII. Disease is anaplastic lymphoma kinase (ALK)-positive (NCCN 2A);**AND**
XVIII. Individual is using as a single-agent treatment;

OR

XIX. Individual has a diagnosis of Soft Tissue Sarcoma; **AND**
XX. Disease is anaplastic lymphoma kinase (ALK)-positive (NCCN 2A); **AND**
XXI. Individual is using as a single-agent treatment;

OR

XXII. Individual has a diagnosis of pediatric diffuse high-grade glioma (NCCN 2A); **AND**
XXIII. Disease is anaplastic lymphoma kinase (ALK)-positive; **AND**
XXIV. Individual is using for adjuvant treatment or for recurrent or progressive disease.

Key References:

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2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Fukano R, Mori T, Sekimizu M, et al. Alectinib for relapsed or refractory anaplastic lymphoma kinase-positive anaplastic large cell lymphoma: An open-label phase II trial. *Cancer Sci*. 2020;111(12):4540-4547. doi:10.1111/cas.14671 Available at https://www-ncbi-nlm-nih-gov.uc.idm.oclc.org/pmc/articles/PMC7734006/pdf/CAS-111-4540.pdf. Accessed October 5, 2022.
4. Kemps PG, Picarsic J, Durham BH, et al. ALK-positive histiocytosis: a new clinicopathologic spectrum highlighting neurologic involvement and responses to ALK inhibition. *Blood*. 2022;139(2):256-280. doi:10.1182/blood.2021013338 Available at https://www-ncbi-nlm-nih-gov.uc.idm.oclc.org/pmc/articles/PMC8759533/. Accessed October 5, 2022.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
6. 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
7. 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
8. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed October 1, 2025.
    a. B-Cell Lymphomas. V3.2025. Revised August 18, 2025.
    b. Central Nervous System Cancers. V2.2025. Revised August 28, 2025.
    c. Histiocytic Neoplasms. V1.2025. Revised June 20, 2025.
    d. Non-Small Cell Lung Cancer. V8.2025. Revised August 15, 2025.
    e. Pediatric Central Nervous System Cancers. V3.2025. Revised September 2, 2025.
    f. Soft Tissue Sarcoma. V1.2025. Revised May 2, 2025.
    g. T-Cell Lymphomas. V2.2025. Revised May 28, 2025.
    h. Uterine Neoplasms. V3.2025. Revised March 7, 2025.