

Alecensa[®] (alectinib) (Oral)

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Alecensa 150 mg capsule: 8 capsules per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- Anaplastic Large Cell Lymphoma: 600 mg per day
- All other indications: 1200 mg per day

III. Initial Approval Criteria¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria^{1,2}

- Used as a single agent; **AND**
- Patient has anaplastic lymphoma kinase (ALK)-positive disease as detected by an FDA-approved or CLIA compliant test[‡]; **AND**

Non-Small Cell Lung Cancer † Φ^{1,2}

- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
 - Used as first-line therapy; **OR**
 - Used in patients who are intolerant to crizotinib; **OR**
 - Used as subsequent therapy following disease progression on first-line therapy with crizotinib; **OR**
 - Used as continuation of therapy following disease progression on first-line therapy with alectinib, except in cases of symptomatic systemic disease with multiple lesions

Central Nervous System (CNS) Cancers ‡²

- Patient has brain metastases from non-small cell lung cancer; **AND**
 - Used as initial treatment in patients with small asymptomatic brain metastases; **OR**
 - Used for relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options; **OR**
 - Patient has recurrent limited brain metastases; **OR**
 - Used for recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options

Histiocytic Neoplasms – Erdheim-Chester Disease ‡^{2,7}

- Patient has symptomatic disease; **OR**
- Used for relapsed or refractory disease

Anaplastic Large Cell Lymphoma (ALCL) ‡^{2,8}

- Used as subsequent or initial palliative intent therapy for relapsed or refractory disease
- ❖ *If confirmed using an immunotherapy assay* <http://www.fda.gov/CompanionDiagnostics>

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria¹

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hepatotoxicity (severe elevations in ALT/AST or bilirubin), severe myalgia, bradycardia, interstitial lung disease/pneumonitis, severe elevations in creatine phosphokinase (CPK), severe renal impairment, hemolytic anemia, etc.; **AND**

Non-Small Cell Lung Cancer (continuation of therapy following disease progression)

- *Refer to Section III for criteria*

V. Dosage/Administration^{1,6-8}

Indication	Dose
Anaplastic Large Cell Lymphoma	<ul style="list-style-type: none">• Body weight \geq 35 kg: Administer 300 mg (2 capsules) by mouth twice daily until disease progression or unacceptable toxicity.• Body weight $<$ 35 kg: Administer 150 mg (1 capsule) by mouth twice daily until disease progression or unacceptable toxicity.

NSCLC, CNS Cancers, Histiocytic Neoplasms – Erdheim-Chester Disease	Administer 600 mg (4 capsules) by mouth twice daily until disease progression or unacceptable toxicity.
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VI. Billing Code/Availability Information

HCPCS Code:

- J8999: Prescription drug, oral, chemotherapeutic, not otherwise specified
- C9399: Unclassified drugs or biologicals (*Hospital Outpatient Use ONLY*)

NDC:

- Alecensa 150 mg capsule: 50242-0130-xx

VII. References

1. Alecensa [package insert]. South San Francisco, CA. Genentech USA, Inc., September 2021. Accessed June 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for alectinib. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2022.
3. Gadgeel S, Peters S, Mok T, et al. Alectinib versus crizotinib in treatment-naive anaplastic lymphoma kinase-positive (ALK+) non-small-cell lung cancer: CNS efficacy results from the ALEX study. *Ann Oncol.* 2018 Nov 1;29(11):2214-2222. doi: 10.1093/annonc/mdy405.
4. Shaw AT, Gandhi L, Gadgeel S, et al; study investigators. Alectinib in ALK-positive, crizotinib-resistant, non-small-cell lung cancer: a single-group, multicentre, phase 2 trial. *Lancet Oncol.* 2016 Feb;17(2):234-242. doi: 10.1016/S1470-2045(15)00488-X. Epub 2015 Dec 19. Erratum in: *Lancet Oncol.* 2017 Mar;18(3):e134.
5. Gadgeel SM, Shaw AT, Govindan R, et al. Pooled Analysis of CNS Response to Alectinib in Two Studies of Pretreated Patients With ALK-Positive Non-Small-Cell Lung Cancer. *J Clin Oncol.* 2016 Dec;34(34):4079-4085. Epub 2016 Oct 31. Erratum in: *J Clin Oncol.* 2017 May 10;35(14):1631.
6. Gandhi L, Ou SI, Shaw AT, et al. Efficacy of alectinib in central nervous system metastases in crizotinib-resistant ALK-positive non-small-cell lung cancer: Comparison of RECIST 1.1 and RANO-HGG criteria. *Eur J Cancer.* 2017;82:27-33. doi:10.1016/j.ejca.2017.05.019.
7. Kemps P, Picarsic J, Durham B, et al. ALK-positive histiocytosis: a new clinicopathologic spectrum highlighting neurologic involvement and responses to ALK inhibition. *Blood* (2022) 139 (2): 256–280. <https://doi.org/10.1182/blood.2021013338>
8. 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 Dec;111(12):4540-4547. doi: 10.1111/cas.14671. Epub 2020 Oct 28.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C79.31	Secondary malignant neoplasm of brain
C84.40	Peripheral T-cell lymphoma, not classified, unspecified site
C84.41	Peripheral T-cell lymphoma, not classified, lymph nodes of head, face, and neck
C84.42	Peripheral T-cell lymphoma, not classified, intrathoracic lymph nodes
C84.43	Peripheral T-cell lymphoma, not classified, intra-abdominal lymph nodes
C84.44	Peripheral T-cell lymphoma, not classified, lymph nodes of axilla and upper limb
C84.45	Peripheral T-cell lymphoma, not classified, lymph nodes of inguinal region and lower limb
C84.46	Peripheral T-cell lymphoma, not classified, intrapelvic lymph nodes
C84.47	Peripheral T-cell lymphoma, not classified, spleen
C84.48	Peripheral T-cell lymphoma, not classified, lymph nodes of multiple sites
C84.49	Peripheral T-cell lymphoma, not classified, extranodal and solid organ sites
C84.60	Anaplastic large cell lymphoma, ALK-positive, unspecified site
C84.61	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of head, face, and neck
C84.62	Anaplastic large cell lymphoma, ALK-positive, intrathoracic lymph nodes
C84.63	Anaplastic large cell lymphoma, ALK-positive, intra-abdominal lymph nodes
C84.64	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of axilla and upper limb

ICD-10	ICD-10 Description
C84.65	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of inguinal region and lower limb
C84.66	Anaplastic large cell lymphoma, ALK-positive, intrapelvic lymph nodes
C84.67	Anaplastic large cell lymphoma, ALK-positive, spleen
C84.68	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of multiple sites
C84.69	Anaplastic large cell lymphoma, ALK-positive, extranodal and solid organ sites
C84.70	Anaplastic large cell lymphoma, ALK-negative, unspecified site
C84.71	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of head, face, and neck
C84.72	Anaplastic large cell lymphoma, ALK-negative, intrathoracic lymph nodes
C84.73	Anaplastic large cell lymphoma, ALK-negative, intra-abdominal lymph nodes
C84.74	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of axilla and upper limb
C84.75	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of inguinal region and lower limb
C84.76	Anaplastic large cell lymphoma, ALK-negative, intrapelvic lymph nodes
C84.77	Anaplastic large cell lymphoma, ALK-negative, spleen
C84.78	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of multiple sites
C84.79	Anaplastic large cell lymphoma, ALK-negative, extranodal and solid organ sites
C86.2	Enteropathy-type (intestinal) T-cell lymphoma
C86.5	Angioimmunoblastic T-cell lymphoma
D76.3	Other histiocytosis syndromes
Z85.118	Personal history of other malignant neoplasm of bronchus and lung

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs), and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.

ALECENSA® (alectinib) Prior Auth Criteria

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC