

Alecensa[®] (alectinib) (Oral)

Document Number: IC-0263

Last Review Date: 05/02/2024

Date of Origin: 01/26/2016

Dates Reviewed: 01/2016, 01/2017, 11/2017, 07/2018, 07/2019, 07/2020, 07/2021, 07/2022, 07/2023, 05/2024

I. Length of Authorization ¹

Coverage will be provided for 6 months and may be renewed, unless otherwise specified.

- Adjuvant therapy for NSCLC can be authorized up to a maximum of two (2) years of therapy.

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 Criteria ¹

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**

Large B-Cell Lymphoma ^{‡ 2,9}

- Used for relapsed or refractory disease

Central Nervous System (CNS) Cancers ^{‡ 2,6}

- 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

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; **OR**
- Patient has had complete resection of Stage IB (tumors ≥ 4 cm) to Stage IIIA disease; **AND**
 - Used as adjuvant therapy

Soft Tissue Sarcoma – Inflammatory Myofibroblastic Tumor (IMT) ‡²

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

- Used as subsequent or initial palliative intent therapy for relapsed or refractory disease

Uterine Neoplasms - Uterine Sarcoma ‡²

- Patient has inflammatory myofibroblastic tumor (IMT); **AND**
- Patient has advanced, recurrent/metastatic, or inoperable disease; **AND**
- Used as first-line therapy OR as subsequent therapy if not previously used

❖ *If confirmed using an immunotherapy assay- <http://www.fda.gov/CompanionDiagnostics>*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria^{1,2}

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), bradycardia, interstitial lung disease (ILD)/pneumonitis, severe myalgia and creatine phosphokinase (CPK) elevation, severe renal impairment, hemolytic anemia, etc.

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

- *Refer to Section III for criteria*

Non-Small Cell Lung Cancer (adjuvant therapy)

- Patient has not exceeded a maximum of two (2) years of therapy

V. Dosage/Administration ^{1,6-11}

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	<p><u>Adjuvant treatment</u></p> <ul style="list-style-type: none"> • Administer 600 mg (4 capsules) by mouth twice daily for a total of 2 years or until disease recurrence or unacceptable toxicity. <p><u>All other treatment settings</u></p> <ul style="list-style-type: none"> • Administer 600 mg (4 capsules) by mouth twice daily until disease progression or unacceptable toxicity.
All Other Indications	Administer 600 mg (4 capsules) by mouth twice daily until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCP/CS Code(s):

- J8999: Prescription drug, oral, chemotherapeutic, not otherwise specified
- C9399: Unclassified drugs or biologicals

NDC:

- Alecensa 150 mg capsule: 50242-0130-xx

VII. References

1. Alecensa [package insert]. South San Francisco, CA. Genentech USA, Inc., April 2024. Accessed April 2024.

2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for alectinib. National Comprehensive Cancer Network, 2023. 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 2023.
3. Gadgeel S, Peters S, Mok T, et al. Alectinib versus crizotinib in treatment-naïve 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.
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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.
9. Soumerai JD, Rosenthal A, Harkins S, et al. Next-generation ALK inhibitors are highly active in ALK-positive large B-cell lymphoma. *Blood.* 2022 Oct 20;140(16):1822-1826. doi: 10.1182/blood.2022015443.
10. Peters S, Camidge DR, Shaw AT, et al; ALEX Trial Investigators. Alectinib versus Crizotinib in Untreated ALK-Positive Non-Small-Cell Lung Cancer. *N Engl J Med.* 2017 Aug 31;377(9):829-838. doi: 10.1056/NEJMoa1704795.
11. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Uterine Neoplasms. Version 2.2023. National Comprehensive Cancer Network, 2023. 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 2023.
12. Solomon BJ, Ahn JS, Barlesi F, et al. ALINA: A phase III study of alectinib versus chemotherapy as adjuvant therapy in patients with stage IB–IIIA anaplastic lymphoma kinase-positive (ALK+) non-small cell lung cancer (NSCLC).. *JCO* 37, TPS8569-TPS8569(2019). DOI:10.1200/JCO.2019.37.15_suppl.TPS8569.

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
C48.0	Malignant neoplasm of retroperitoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified
C79.31	Secondary malignant neoplasm of brain
C83.30	Diffuse large B-cell lymphoma, unspecified site

ICD-10	ICD-10 Description
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites
C83.90	Non-follicular (diffuse) lymphoma, unspecified, unspecified site
C83.91	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of head, face, and neck
C83.92	Non-follicular (diffuse) lymphoma, unspecified, intrathoracic lymph nodes
C83.93	Non-follicular (diffuse) lymphoma, unspecified, intra-abdominal lymph nodes
C83.94	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of axilla and upper limb
C83.95	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of inguinal region and lower limb
C83.96	Non-follicular (diffuse) lymphoma, unspecified, intrapelvic lymph nodes
C83.97	Non-follicular (diffuse) lymphoma, unspecified, spleen
C83.98	Non-follicular (diffuse) lymphoma, unspecified, lymph nodes of multiple sites
C83.99	Non-follicular (diffuse) lymphoma, unspecified, extranodal and solid organ sites
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
C85.20	Mediastinal (thymic) large B-cell lymphoma, unspecified site
C85.21	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face, and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes
C85.23	Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma, spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma, 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
Z85.42	Personal history of malignant neoplasm of other parts of uterus
Z85.831	Personal history of malignant neoplasm of soft tissue

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied 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.
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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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