

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Alecensa Prior Authorization Policy

- Alecensa[®] (alectinib capsules – Genentech)

REVIEW DATE: 01/17/2024; selected revision 05/08/2024

OVERVIEW

Alecensa, a tyrosine kinase inhibitor, is indicated for **Non-Small Cell Lung Cancer (NSCLC)** for the following in adults:

- Adjuvant treatment following tumor resection of *ALK*-positive NSCLC (tumors ≥ 4 cm or node positive), as detected by an FDA-approved test.
- Treatment of anaplastic lymphoma kinase (*ALK*)-positive, metastatic disease as detected by an FDA-approved test.¹

GUIDELINES

Alecensa has been addressed in National Comprehensive Cancer Network (NCCN) guidelines:²

- **B-Cell Lymphomas:** Guidelines (version 1.2024 – January 18, 2024) recommend Alecensa (category 2A) for relapsed or refractory *ALK*-positive large B-cell lymphomas.⁷
- **Histiocytic Neoplasms:** Guidelines (version 1.2023 – August 11, 2023) recommend Alecensa as a “useful in certain circumstances” treatment option for *ALK*-positive Erdheim-Chester Disease (category 2A).³
- **Non-Small Cell Lung Cancer:** Guidelines (version 5.2024 – April 23, 2024) recommend testing for *ALK* rearrangements in eligible patients with NSCLC.⁴ Alecensa is recommended for 24 months in patients with completely resected stage II-IIIa or stage IIIB (T3, N2) NSCLC, if positive for *ALK* rearrangement (category 1). If *ALK* rearrangement is discovered prior to first-line systemic therapy for advanced or metastatic disease, Alecensa is a “preferred” first-line treatment option (category 1). If *ALK* rearrangement is discovered during first-line systemic therapy, options are to complete the planned systemic therapy (including maintenance therapy) or to interrupt the systemic therapy and treat with Alecensa (“preferred”, category 2A) or another *ALK* inhibitor. NCCN recommendations for patients with disease progression often include continuing the first-line targeted therapy, depending on type of progression.
- **T-Cell Lymphomas:** Guidelines (version 1.2024 – December 21, 2023) recommend Alecensa as a treatment option for initial palliative-intent therapy in *ALK*-positive disease or for patients with relapsed or refractory *ALK*-positive anaplastic large cell lymphoma (ALCL).⁵ NCCN notes a phase II study involving patients ≥ 6 years of age with relapsed or refractory *ALK*-positive ALCL. However, this was a small study involving 10 patients with a median age of 19.5 years.
- **Uterine Neoplasms:** Guidelines (version 1.2024 – September 20, 2023) recommend Alecensa as a treatment option for patients with inflammatory myofibroblastic tumor with *ALK* translocation (category 2A).⁶

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Alecensa. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Alecensa is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets the following (A, B, C, and D):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient meets ONE of the following (i or ii):
 - i. The medication is used as adjuvant treatment following tumor resection; OR
Note: For tumors ≥ 4 cm or node positive.
 - ii. Patient has advanced or metastatic disease; AND
 - C) Patient has anaplastic lymphoma kinase (*ALK*)-positive disease; AND
 - D) The mutation was detected by an approved test.

Other Uses with Supportive Evidence

2. **Anaplastic Large Cell Lymphoma.** Approve for 1 year if the patient meets the following (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has anaplastic lymphoma kinase (*ALK*)-positive disease; AND
 - C) Patient meets one of the following (i or ii):
 - i. The medication is used for palliative-intent therapy; OR
 - ii. Patient has relapsed or refractory disease.
 3. **Erdheim-Chester Disease.** Approve for 1 year if the patient meets the following (A and B):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has anaplastic lymphoma kinase (*ALK*) rearrangement/fusion-positive disease.
 4. **Inflammatory Myofibroblastic Tumor.** Approve for 1 year if the patient meets the following (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has anaplastic lymphoma kinase (*ALK*)-positive disease; AND
 - C) Patient meets one of the following (i or ii):
 - i. Patient has advanced, recurrent, or metastatic disease; OR
 - ii. The tumor is inoperable.
 5. **Large B-Cell Lymphoma.** Approve for 1 year if the patient meets the following (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has anaplastic lymphoma kinase (*ALK*)-positive disease; AND
 - C) Patient has relapsed or refractory disease.
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CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Alecensa is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Alecensa® capsules [prescribing information]. South San Francisco, CA: Genentech; April 2024.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 16, 2024. Search term: alectinib.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 1.2023 – August 11, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 14, 2024.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 5.2024 – April 23, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on May 2, 2024.
5. The NCCN T-Cell Lymphoma Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 16, 2024.
6. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2024 – September 10, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 14, 2024.
7. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 1.2024 – January 18, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 19, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	Inflammatory Myofibroblastic Tumor: This new condition of approval was added to the policy	01/11/2023
Annual Revision	Anaplastic Large Cell Lymphoma: Added criterion that the medication can be used for palliative-intent therapy based on guideline recommendations. Large B-Cell Lymphoma: This condition and criteria for approval was added to the policy under “Other Uses with Supportive Evidence”.	01/17/2024
Selected Revision	Non-Small Cell Lung Cancer: Added criterion for adjuvant treatment after tumor resection based on new indication approval.	05/08/2024