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.

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.