PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Alecensa Prior Authorization Policy
- Alecensa® (alectinib capsules – Genentech)

REVIEW DATE: 01/11/2023

OVERVIEW
Alecensa, a tyrosine kinase inhibitor, is indicated for the treatment of patients with anaplastic lymphoma kinase (*ALK*)-positive, metastatic **non-small cell lung cancer (NSCLC)**, as detected by an FDA-approved test.[1]

GUIDELINES
Alecensa has been addressed in National Comprehensive Cancer Network (NCCN) guidelines:[2]
- **Histiocytic Neoplasms:** Guidelines (version 1.2022 – May 20, 2022) 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 1.2023 – December 22, 2022) recommend testing for *ALK* rearrangements in eligible patients with NSCLC.[4] If *ALK* rearrangement is discovered prior to first-line systemic therapy, 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 1.2023 – January 5, 2023) recommend Alecensa as a treatment option 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 1.2023 – December 22, 2022) 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 criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** 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 criteria (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 criteria (i or ii):
     - **i.** Patient has relapsed disease; OR
     - **ii.** Patient has refractory disease.

3. **Erdheim-Chester Disease.** Approve for 1 year if the patient meets the following criteria (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 criteria (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 criteria (i or ii):
     - **i.** Patient has advanced, recurrent, or metastatic disease; OR
     - **ii.** The tumor is inoperable.

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; September 2021.
2. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 10, 2023. Search term: alectinib.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 1.2022 – May 20, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 9, 2023.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – December 22, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 9, 2023.
5. The NCCN T-Cell Lymphoma Clinical Practice Guidelines in Oncology (version 1.2023 – January 5, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 9, 2023.
6. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2023 – December 22, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 9, 2023.