

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Alecensa Prior Authorization Policy

• Alecensa[®] (alectinib capsules – Genentech)

REVIEW DATE: 03/02/2022

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:^{2,3}

- Non-Small Cell Lung Cancer: Guidelines (version 1.2022 December 7, 2021) recommend Alecensa as a preferred first-line therapy (category 1) for the treatment of ALK-positive NSCLC.² Alecensa is also recommended for use as a subsequent therapy for patients who progress on first-line therapy. NCCN recommends testing for ALK fusions in patients with metastatic nonsquamous NSCLC.
- **T-Cell Lymphomas:** Guidelines (version 1.2022 December 22, 2021) recommend Alecensa as initial palliative intent therapy for ALK-positive anaplastic large cell lymphoma (ALCL).³ Alecensa is also recommended as second-line and subsequent therapy for ALK-positive ALCL.

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 3 years if the patient meets the following criteria (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - **B)** Patient has metastatic disease; AND
 - C) Patient has anaplastic lymphoma kinase (ALK)-positive non-small cell lung disease.

Other Uses with Supportive Evidence

- 2. Anaplastic Large Cell Lymphoma. Approve for 3 years 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)-positive 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; September 2021.
- The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 1.2022 December 7, 2021).
 2021 National Comprehensive Cancer Network, Inc. Available at: <u>http://www.nccn.org</u>. Accessed on February 28, 2022.
- 3. The NCCN T-Cell Lymphoma Clinical Practice Guidelines in Oncology (version 1.2022 December 22, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: <u>http://www.nccn.org</u>. Accessed on February 28, 2022.