

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Alecensa® (alectinib capsules – Genentech)

TAC APPROVAL DATE: 01/30/2019

OVERVIEW

Alecensa, a tyrosine kinase inhibitor (TKI), is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC).¹ Alecensa targets ALK and RET; it also has a major active metabolite, M4, which demonstrated similar *in vitro* potency and activity as alectinib.

GUIDELINES

According to the National Comprehensive Cancer Network (NCCN) NSCLC guidelines (version 3.2019 – January 18, 2019), Alecensa (preferred), Xalkori® (crizotinib capsules), Alunbrig™ (brigatinib tablets), or Zykadia™ (ceritinib capsules) are the recommended first-line therapies for ALK-positive NSCLC (all category 1).² For subsequent therapy after progression on Xalkori, local therapy, continuing Xalkori therapy, or switching therapy to Zykadia, Alunbrig, or Alecensa (all category 2A) is recommended. For multiple systemic lesions Zykadia, Alecensa, or Alunbrig (all if not previously given) are recommended or initial cytotoxic therapy options can be used. Upon further progression on Xalkori and one of Zykadia, Alecensa, or Alunbrig, Lorbrena (lorlatinib tablets) can be used. For progression on one of Alecensa, Zykadia, or Alunbrig as first-line therapy, Lorbrena can be used upon progression (category 2A).

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Alecensa. All approvals are provided for 3 years in duration unless otherwise noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

- 1. Non-Small Cell Lung Cancer (NSCLC).** Approve for 3 years if the patient has *metastatic* anaplastic lymphoma kinase (ALK)-positive NSCLC as detected by an approved test.
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CONDITIONS NOT RECOMMENDED FOR APPROVAL

Alecensa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

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; November 2017.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 3.2019 – January 18, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed January 28, 2019.

HISTORY

| Type of Revision | Summary of Changes* | TAC Approval Date |
|-------------------|---|-------------------|
| New Policy | -- | 01/20/2016 |
| Annual revision | No criteria changes | 01/25/2017 |
| Selected revision | Added approval criteria for first-line setting based on a Phase III trial. Added “after Xalkori therapy” qualifier to indication description for FDA-approved use. | 06/14/2017 |
| Annual revision | Deleted approval criteria for “After Xalkori Therapy” since Alecensa is approved in first-line setting. Deleted qualifier “First-Line Therapy” and moved criteria from Other Uses to FDA-Approved Indications. Added “as detected by an approved test” to criteria to check for ALK-positive NSCLC. | 01/24/2018 |
| Annual revision | No criteria changes | 01/30/2019 |
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TAC – Therapeutic Assessment Committee; * For a further summary of criteria changes, refer to respective TAC minutes available at: <http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx>; ALK – Anaplastic lymphoma kinase; NSCLC – Non-small cell lung cancer.
