

PRIOR AUTHORIZATION POLICY

- POLICY:** Oncology – Zykadia Prior Authorization Policy
- Zykadia® (ceritinib capsules and tablets – Novartis)

REVIEW DATE: 06/30/2021

OVERVIEW

Zykadia, a kinase inhibitor, is indicated for the treatment of adult patients with metastatic **non-small cell lung cancer** (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.¹

Biochemical and/or cellular assays show targets of Zykadia inhibition (at clinically relevant concentrations) include ALK, insulin-like growth factor 1 receptor (IGF-1R), insulin receptor (InsR), and ROS proto-oncogene 1 (ROS1).¹ Among these receptors, Zykadia is most active against ALK.

GUIDELINES

Zykadia is addressed in National Comprehensive Cancer Network (NCCN) guidelines:²⁻⁴

- **NSCLC.** The NCCN NSCLC guidelines (version 5.2021 – June 15, 2021) recommend testing for ALK fusions in patients with metastatic nonsquamous NSCLC.² NCCN recommends Alecensa® (alectinib capsules), Alunbrig® (brigatinib tablets), and Lorbrina® (lorlatinib tablets) as first-line treatment options (category 1) for patients with ALK rearrangement-positive NSCLC. Zykadia is listed as an “Other Recommended” first-line treatment option (category 1). NCCN recommends ROS1 testing in patients with metastatic nonsquamous NSCLC or NSCLC nonspecific. First-line treatment options for ROS1 rearrangement-positive NSCLC include Xalkori® (crizotinib capsules), Rozlytrek™ (entrectinib capsules), and Zykadia (all are category 2A). Xalkori and Rozlytrek are the preferred first-line treatment options because they have been evaluated in more patients, they are approved by the FDA for this use, and they are better tolerated. Zykadia is listed as an “Other Recommended” first-line treatment option (category 2A).
- **Soft Tissue Sarcoma.** The NCCN Soft Tissue Sarcoma guidelines (version 2.2021 – April 28, 2021) recommend Zykadia, Alunbrig® (brigatinib tablets), and Xalkori® (crizotinib capsules) as preferred treatment options for patients with inflammatory myofibroblastic tumor with ALK translocation (category 2A recommendation).³

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

- 1. Non-Small Cell Lung Cancer (NSCLC) – Anaplastic Lymphoma Kinase (ALK)-Positive.** 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 metastatic anaplastic lymphoma kinase (*ALK*)-positive NSCLC as detected by an approved test.

Other Uses with Supportive Evidence

- 2. Non-Small Cell Lung Cancer (NSCLC) with ROS1 Rearrangement.** 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 ROS1 rearrangement-positive NSCLC; AND
 - C) Patient is receiving Zykadia as first-line treatment.

Note: NCCN does not list Zykadia as an option for subsequent treatment of patients with NSCLC with ROS1 rearrangement.
- 3. Soft Tissue Sarcoma – Inflammatory Myofibroblastic Tumor (IMT).** Approve for 3 years if the patients meets the following criteria (A and B):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has IMT with anaplastic lymphoma kinase (ALK) translocation.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Zykadia 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. Zykadia[®] capsules and tablets [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; March 2019.
 2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 5.2021 – June 15, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on June 25, 2021.
 3. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2021 – April 28, 2021). ©2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on June 25, 2021.
 4. The NCCN Drugs & Biologics Compendium. © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on June 25, 2021. Search terms: ceritinib.
-