

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Zykadia Prior Authorization Policy

- Zykadia® (ceritinib capsules and tablets – Novartis)

REVIEW DATE: 08/07/2024

OVERVIEW

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

GUIDELINES

Zykadia is addressed in National Comprehensive Cancer Network (NCCN) guidelines:²⁻⁵

- **Histiocytic Neoplasms:** Guidelines (version 2.2024 – July 19, 2024) recommend Zykadia as a “Useful in Certain Circumstances” treatment option for *ALK*-positive Erdheim-Chester Disease (category 2A).³
- **Inflammatory Myofibroblastic Tumor (IMT):** NCCN Soft Tissue Sarcoma guidelines (version 2.2024 – July 31, 2024) recommend Zykadia as a “Preferred” treatment option for IMT with *ALK* translocation (category 2A). The NCCN Uterine Neoplasms guidelines (version 2.2024 – March 6, 2024) recommend Zykadia as “Useful in Certain Circumstances” for first-line therapy for advanced, recurrent/metastatic, or inoperable IMT with *ALK* translocation (category 2A) for uterine sarcoma.^{5,6}
- **NSCLC:** Guidelines (version 7.2024 – July 26, 2024) recommend testing for biomarkers (e.g., *ALK* rearrangement, *ROS* proto-oncogene 1 (*ROS1*) gene rearrangement) in eligible patients with NSCLC.⁴
 - *ALK* rearrangement-positive NSCLC: If *ALK* rearrangement is discovered prior to first-line systemic therapy, Zykadia is an “Other Recommended Regimen” (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 Zykadia (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.
 - *ROS1* rearrangement-positive NSCLC: If *ROS1* rearrangement is discovered prior to first-line systemic therapy, Zykadia is an “Other Recommended” first-line treatment option (category 2A). If *ROS1* rearrangement is discovered during first-line systemic therapy, options are to complete the planned systemic therapy (including maintenance therapy) or interrupt and treat with Zykadia (category 2A). For patients who progress on treatment, if they are asymptomatic, they may continue to receive the treatment they were previously receiving (including Zykadia) or switch to Lorbrena® (lorlatinib tablets). There are different recommendations for patients who are symptomatic, depending on type of progression.
- **T-Cell Lymphomas:** Guidelines (version 4.2024 – May 28, 2024) recommend Zykadia for *ALK*-positive anaplastic large-cell lymphoma (ALCL) under “other recommended regimens” (category 2A) for initial palliative-intent therapy and for second-line/subsequent therapy (regardless of intention to transplant).

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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 one of the following criteria:

FDA-Approved Indication

- 1. Non-Small Cell Lung Cancer (NSCLC) – Anaplastic Lymphoma Kinase (ALK)-Positive.** Approve for 1 year if the patient meets ALL of the following (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 is detected by an approved test.

Other Uses with Supportive Evidence

- 2. Erdheim-Chester Disease.** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease.
- 3. Inflammatory Myofibroblastic Tumor.** Approve for 1 year if the patients meets ALL of 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.
- 4. Non-Small Cell Lung Cancer with ROS1 Rearrangement.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has advanced or metastatic disease; AND
 - C) Patient has ROS1 rearrangement-positive disease.
- 5. Peripheral T-Cell Lymphomas.** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has anaplastic lymphoma kinase (ALK)-positive anaplastic large cell lymphoma (ALCL).

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; October 2021.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 1, 2024. Search terms: ceritinib.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 2.2024 – July 19, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 1, 2024.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 7.2024 – June 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 1, 2024.
5. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2024 – July 31, 2024). ©2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 1, 2024.
6. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2024 – March 6, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 1, 2024.
7. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 4.2024 – May 28, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 1, 2024.