PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 07/13/2022; selected revision 01/11/2023

OVERVIEW

Zykadia, a kinase inhibitor, is indicated for the treatment of adults with metastatic **non-small cell lung cancer** (NSCLC) 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 1.2022 – May 20, 2022) recommend Zykadia as a "useful in certain circumstances" treatment option for *ALK*-positive Erdheim-Chester Disease (category 2A).[3]
- **NSCLC:** Guidelines (version 1.2023 – December 22, 2023) 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 therapy" (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.
- **Inflammatory Myofibroblastic Tumor (IMT):** NCCN Soft Tissue Sarcoma guidelines (version 2.2022 – May 17, 2022) and NCCN Uterine Neoplasms guidelines (version 1.2023 – December 22, 2022) recommend Zykadia as a treatment option for IMT with *ALK* translocation.5,6

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 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 is detected by an approved test.

Other Uses with Supportive Evidence

2. **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.

3. **Inflammatory Myofibroblastic Tumor.** Approve for 1 year if the patients 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.

4. **Non-Small Cell Lung Cancer with *ROS1* Rearrangement.** 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 advanced or metastatic disease; AND
   - **C)** Patient has *ROS1* rearrangement-positive disease.

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. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 5, 2022. Search terms: ceritinib.
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 July 7, 2022.
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 Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2022 – May 17, 2022). ©2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 5, 2022.
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.