Reference number(s)
1668-A

SPECIALTY GUIDELINE MANAGEMENT

ZYKADIA (ceritinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Zykadia 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.

B. Compendial Uses
1. NSCLC, recurrent, advanced or metastatic ALK rearrangement-positive or ROS1 rearrangement-positive tumors
2. Inflammatory myofibroblastic tumor (IMT) with ALK translocation
3. Brain metastases from ALK rearrangement-positive NSCLC as a single agent

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: ALK mutation or translocation status or ROS-1 mutation status (where applicable).

III. CRITERIA FOR INITIAL APPROVAL

A. Non-Small Cell Lung Cancer (NSCLC)
Authorization of 12 months may be granted for treatment of NSCLC as a single agent when the member meets either of the following criteria:
1. Member has recurrent, advanced or metastatic ALK-positive NSCLC (including brain metastases from NSCLC).
2. Member has recurrent, advanced or metastatic ROS1-positive NSCLC.

B. Inflammatory Myofibroblastic Tumor (IMT)
Authorization of 12 months may be granted for treatment of ALK-positive IMT as a single agent.

IV. CONTINUATION OF THERAPY

A. Non-Small Cell Lung Cancer (NSCLC)

Authorization of 12 months may be granted for continued treatment of non-small cell lung cancer (NSCLC) in members requesting reauthorization when there is no evidence of unacceptable toxicity while on the current regimen.

B. All Other Indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for all other indications listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen

V. REFERENCES

1. Zykadia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp; October 2021.
2. The NCCN Drugs & Biologics Compendium 2022 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 16, 2022.