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 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
2. Inflammatory myofibroblastic tumor (IMT) with ALK translocation

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Non-small cell lung cancer (NSCLC)
Authorization of 12 months may be granted for treatment of recurrent or metastatic ALK-positive NSCLC.

B. Inflammatory myofibroblastic tumor (IMT)
Authorization of 12 months may be granted for treatment of ALK-positive IMT.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Zykadia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp; May 2017.
2. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 27, 2017.
3. The NCCN Clinical Practice Guidelines in Oncology® Non-Small Cell Lung Cancer (Version 4.2017).© 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 27, 2017.