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 anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib.

B. Compendial Uses
   1. Recurrent NSCLC
   2. Inflammatory myofibroblastic tumor (IMT) with ALK translocation

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

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review: Anaplastic lymphoma kinase (ALK) mutation status

III. CRITERIA FOR INITIAL APPROVAL

A. Non-Small Cell Lung Cancer (NSCLC)
   Authorization of 12 months may be granted for treatment of recurrent or metastatic NSCLC when all of the following criteria are met:
   a. The tumor is ALK-positive.
   b. Member has progressed on prior therapy with crizotinib (Xalkori) OR member has experienced intolerance to crizotinib (Xalkori).
   c. Zykadia is used as a single agent.

B. Inflammatory myofibroblastic tumor (IMT)
   Authorization of 12 months may be granted for treatment of ALK-positive IMT in members who are prescribed Zykadia as a single agent.

IV. CONTINUATION OF THERAPY

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

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The following dosing limits apply: 750 mg per day.

VI. REFERENCES