

Clinical Pharmacy Program Guidelines for Zykadia

Program	Prior Authorization
Medication	Zykadia™ (ceritinib)
Pharmacy & Therapeutics Approval Date	7/2014, 7/2015, 6/2016
Effective Date	9/1/2016

1. Background:

Zykadia™ (ceritinib) is a kinase inhibitor 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 Xalkori® (crizotinib). This indication is approved under accelerated approval based on tumor response rate and duration of response. An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.¹ The National Cancer Comprehensive Network (NCCN) also recommends Zykadia for the treatment of inflammatory myofibroblastic tumor (IMT) with ALK translocation.²

2. Coverage Criteria:

<p>A. <u>Non-Small Cell Lung Cancer (NSCLC)</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Zykadia will be approved based on all of the following criteria:</p> <p style="margin-left: 40px;">(1) Diagnosis of non-small cell lung cancer (NSCLC)</p> <p style="text-align: center; margin-left: 100px;">-AND-</p> <p style="margin-left: 40px;">(2) One of the following:</p> <p style="margin-left: 80px;">(a) Disease is metastatic</p> <p style="margin-left: 80px;">(b) Disease is recurrent</p> <p style="text-align: center; margin-left: 100px;">-AND-</p> <p style="margin-left: 40px;">(3) Tumor is anaplastic lymphoma kinase (ALK)-positive</p> <p style="text-align: center; margin-left: 100px;">-AND-</p>

(4) History of failure or intolerance to Xalkori (crizotinib)
Authorization will be issued for 12 months.

2. Reauthorization

a. **Zykadia** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Zykadia therapy

Authorization will be issued for 12 months.

B. Soft Tissue Sarcoma [off-label]

1. Initial Authorization

a. **Zykadia** will be approved based on the following criterion:

- (1) Diagnosis of inflammatory myofibroblastic tumor (IMT) with ALK translocation

Authorization will be issued for 12 months.

2. Reauthorization

a. **Zykadia** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Zykadia therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Supply limits may be in place.

4. References:

1. Zykadia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2015.

2. The NCCN Drugs and Biologics Compendium (NCCN Compendium[™]). Available at www.nccn.org. Accessed May 5, 2016.

Program	Prior Authorization - Zykadia (ceritinib)
Change Control	
Date	Change
9/2014	New policy
9/2015	Updated diagnosis verbiage and formatting from “diagnosis of metastatic non-small cell lung cancer” to “diagnosis of non-small cell lung cancer” and “disease is metastatic or recurrent”, per NCCN. Updated initial and reauthorization durations from 7 months to 12 months
6/2016	Updated policy to new template. Updated clinical criteria to align with E&I notification except less than 19 criteria.