UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Zykadia

Program	Prior Authorization
Medication	Zykadia™ (ceritinib)
Issue Date	9/2014
Pharmacy and Therapeutics Approval Date	6/2017
Effective Date	8/2017

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 as first-line therapy for ALK-positive recurrent or metastatic NSCLC and for the treatment of inflammatory myofibroblastic tumor (IMT) with ALK translocation.[2]

2. Coverage Criteria:

A. Non-Small Cell Lung Cancer (NSCLC)

1. Initial Authorization

a. **Zykadia** will be approved based on **all** of the following criteria:

(1) Diagnosis of non-small cell lung cancer (NSCLC)

-AND-

(2) One of the following:

(a) Disease is metastatic
(b) Disease is recurrent

-AND-

(3) Tumor is anaplastic lymphoma kinase (ALK)-positive

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. References:

1. Zykadia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2016.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed April 21, 2017.

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 Employer & Individual notification except less than 19 criteria.
6/2017	Updated background and removed requirement of crizotinib failure to align with NCCN recommendations