

Zykadia™ (ceritinib) (Oral)

Document Number: IC-0201

Last Review Date: 01/2018

Date of Origin: 06/24/2014

Dates Reviewed: 06/2014, 06/2015, 04/2016, 04/2017, 06/2017, 01/2018

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Zykadia 150 mg capsules: 3 capsules per day

B. Max Units (per dose and over time) [Medical Benefit]:

- 450 mg daily

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**
- Must be used as a single agent; **AND**

Non-small Cell Lung Cancer †

- Patient has recurrent or metastatic disease; **AND**
- Patient's disease is anaplastic lymphoma kinase (ALK)-positive as detected by FDA-approved test; **AND**
 - Used as first-line therapy; **OR**
 - Used as subsequent therapy; **AND**
 - Patient has previously failed with, or is intolerant to, treatment with crizotinib; **OR**
 - Continuation of therapy if used first-line (not for asymptomatic disease with rapid radiologic progression or threatened organ function or symptomatic progression with multiple lesions)

Inflammatory Myofibroblastic Tumor (IMT) – Soft Tissue Sarcoma ‡

- Patient's disease has an ALK translocation as detected upon standard laboratory diagnostic tests (e.g., FISH)

Central Nervous System Cancers-Brain Metastases ‡

- Patient had recurrent disease; **AND**
- Zykadia was active against the primary tumor (ALK rearrangement-positive non-small cell lung cancer)

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Tumor response with stabilization or disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: hepatotoxicity, bradycardia, hyperglycemia, QT interval prolongation, Interstitial Lung Disease (ILD)/Pneumonitis, gastrointestinal toxicity and pancreatitis.

V. Dosage/Administration

Indication	Dose
All indications	450 mg orally once daily with food.

VI. Billing Code/Availability Information

Jcode:

- J8999: Prescription drug, oral, chemotherapeutic. Not Otherwise Specified
- C9399: Unclassified drugs or biologicals, Hospital Outpatient use only

NDC:

- Zykadia 150 mg capsule: 00078-0640-xx

VII. References

1. Zykadia [package insert]. East Hanover, NJ: Novartis, December 2017. Accessed January 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for ceritinib. National Comprehensive Cancer Network, 2017. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2018.
3. Shaw AT, Kim DW, Mehra R, et al. Ceritinib in ALK-rearranged non-small-cell lung cancer. N Engl J Med. 2014 Mar 27;370(13):1189-97. doi: 10.1056/NEJMoa1311107.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C33	Malignant neoplasm of trachea

ICD-10	ICD-10 Description
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C79.31	Secondary malignant neoplasm of brain
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.831	Personal history of malignant neoplasm of soft tissue

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC