

# Drug Policy:

## Zykadia™ (ceritinib)

<b>POLICY NUMBER</b> UM ONC_1265	<b>SUBJECT</b> Zykadia™ (ceritinib)		<b>DEPT/PROGRAM</b> UM Dept	<b>PAGE 1 of 3</b>
<b>DATES COMMITTEE REVIEWED</b> 11/12/14, 11/12/14, 04/11/16, 02/06/17, 02/14/18, 02/13/19, 12/11/19, 02/12/20, 11/11/20, 10/13/21, 11/15/21, 12/08/21, 05/11/22, 11/09/22, 11/08/23, 11/13/24	<b>APPROVAL DATE</b> November 13, 2024	<b>EFFECTIVE DATE</b> November 29, 2024	<b>COMMITTEE APPROVAL DATES</b> 11/12/14, 11/12/14, 04/11/16, 02/06/17, 02/14/18, 02/13/19, 12/11/19, 02/12/20, 11/11/20, 10/13/21, 11/15/21, 12/08/21, 05/11/22, 11/09/22, 11/08/23, 11/13/24	
<b>PRIMARY BUSINESS OWNER: UM</b>		<b>COMMITTEE/BOARD APPROVAL</b> Evolut Specialty Services Clinical Guideline Review Committee		
<b>NCQA STANDARDS</b> UM 2		<b>ADDITIONAL AREAS OF IMPACT</b>		
<b>CMS REQUIREMENTS</b>	<b>STATE/FEDERAL REQUIREMENTS</b>		<b>APPLICABLE LINES OF BUSINESS</b> Commercial, Exchange, Medicaid	

### I. PURPOSE

To define and describe the accepted indications for Zykadia (ceritinib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolut is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolut may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

### II. INDICATIONS FOR USE/INCLUSION CRITERIA

#### A. Continuation requests for a not-approvable medication shall be exempt from this Evolut policy provided:

1. The requested medication was used within the last year, **AND**
2. The member has not experienced disease progression and/or no intolerance to the requested medication, **AND**
3. Additional medication(s) are not being added to the continuation request.

#### B. Non-Small Cell Lung Cancer (NSCLC)

1. Zykadia (ceritinib) may be used as monotherapy for first line or subsequent therapy of ALK rearrangement positive metastatic NSCLC.

### III. EXCLUSION CRITERIA

- A. Disease progression while taking Zykadia (ceritinib).
- B. Lack of documentation for the detection of ALK rearrangement by an FDA approved test; a list of the FDA approved test is available at [www.fda.gov/CompanionDiagnostics](http://www.fda.gov/CompanionDiagnostics).
- C. Concurrent use with chemotherapy.
- D. Dosing exceeds single dose limit of Zykadia (ceritinib) 450 mg.
- E. Treatment exceeds the maximum limit of 84 (150 mg) capsules/tablets per month.
- F. Investigational use of Zykadia (ceritinib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
  - 1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
  - 2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
  - 3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
  - 4. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
  - 5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
  - 6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
  - 7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

#### **IV. MEDICATION MANAGEMENT**

- A. Please refer to the FDA label/package insert for details regarding these topics.

#### **V. APPROVAL AUTHORITY**

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

#### **VI. ATTACHMENTS**

- A. None

#### **VII. REFERENCES**

- A. Kim DW, et al. Activity and safety of ceritinib in patients with ALK-rearranged non-small-cell lung cancer (ASCEND-1): updated results from the multicentre, open-label, phase 1 trial. *Lancet Oncol.* 2016 Apr;17(4):452-463. doi: 10.1016/S1470-2045(15)00614-2
- B. Soria JC, et al. First-line ceritinib versus platinum-based chemotherapy in advanced ALK-rearranged non-small-cell lung cancer (ASCEND-4): a randomised, open-label, phase 3 study. *Lancet.* 2017 Mar 4;389(10072):917-929. doi: 10.1016/S0140-6736(17)30123-X
- C. Zykadia prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, New Jersey 2022.
- D. Clinical Pharmacology Elsevier Gold Standard 2024.
- E. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2024.
- F. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2024.
- G. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2024.
- H. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. *J Clin Oncol.* 2014 Apr 20;32(12):1277-80.
- I. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.
- J. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.