

Zykadia (ceritinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Zykadia (ceritinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Zykadia (ceritinib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of recurrent or metastatic non-small cell lung cancer (NSCLC); **AND**
 - II. Disease is anaplastic lymphoma kinase (ALK)-positive (Label, NCCN 1); **OR**
 - III. Individual has progressed on or is intolerant to Xalkori (crizotinib) (NCCN 2A); **OR**
 - IV. Disease is ROS1 rearrangement-positive (NCCN 2A);
- OR**
- V. Individual has a diagnosis of soft tissue sarcoma (Inflammatory Myofibroblastic Tumor) – with ALK mutation (NCCN 2A);
- OR**
- VI. Individual has a diagnosis of advanced, recurrent/metastatic, or inoperable uterine sarcoma; **AND**
 - VII. Has inflammatory myofibroblastic tumor with ALK translocation;
- OR**
- VIII. Individual has a diagnosis of metastatic NSCLC with brain metastases (NCCN 2A); **AND**
 - IX. Individual has a primary diagnosis of ALK-positive NSCLC;
- OR**
- X. Individual has a diagnosis of symptomatic or relapsed/refractory Erdheim-Chester Disease; **AND**
 - XI. Individual is using as a single agent; **AND**
 - XII. Disease is ALK-positive.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 11, 2023

3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Kemps PG, Picarsic J, Durham BH, et al. ALK-positive histiocytosis: a new clinicopathologic spectrum highlighting neurologic involvement and responses to ALK inhibition. *Blood*. 2022;139(2):256-280. doi:10.1182/blood.2021013338 Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8759533/>.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 11, 2023.
 - a. Central Nervous System Cancers. V1.2023. Revised March 4, 2023.
 - b. Histiocytosis Neoplasms. V1.2022. Revised May 20, 2022.
 - c. Non-Small Cell Lung Cancer. V3.2023. Revised April 13, 2023.
 - d. Soft Tissue Sarcoma. V2.2023. Revised April 25, 2023.
 - e. Uterine Neoplasms. V2.2023. Revised April 28, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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