

| Market Applicability |    |    |    |    |    |    |    |
|----------------------|----|----|----|----|----|----|----|
| Market               | DC | GA | KY | MD | NJ | NY | WA |
| Applicable           | X  | X  | X  | X  | X  | X  | X  |

## Zykadia (ceritinib)

| Override(s)                           | Approval Duration |
|---------------------------------------|-------------------|
| Prior Authorization<br>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; **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 (test result confirmed) (NCCN 2A);

**OR**

- VI. Individual has a diagnosis of Central Nervous System Cancers; **AND**
- VII. Individual has a primary diagnosis of ALK-positive NSCLC; **AND**
- VIII. Disease has metastasized to the brain.

### Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. 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: June 14, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on October 3, 2019.

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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| Market               | DC | GA | KY | MD | NJ | NY | WA |
| Applicable           | X  | X  | X  | X  | X  | X  | X  |

- a. Central Nervous System Cancers. V2.2019. Revised September 16, 2019.
- b. Soft Tissue Sarcoma. V4.2019. Revised September 12, 2019.
- c. Non-Small Cell Lung Cancer. V7.2019. Revised August 30, 2019.

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