Clinical Policy: Ceritinib (Zykadia)

Reference Number: PA.CP.PHAR.349
Effective Date: 4.17.19
Last Review Date: 04.19

Revision Log

Description
Ceritinib (Zykadia®) is a tyrosine kinase inhibitor.

FDA Approved Indication(s)
Zykadia is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Zykadia is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (must meet all)**:**

1. Diagnosis of recurrent, advanced or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Meets one of the following (a or b):
   a. Disease is ALK positive;
   b. Disease is ROS1 positive and Zykadia is prescribed as first-line therapy;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 450 mg (3 capsules) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

Approval duration: 6 months

B. Inflammatory Myofibroblastic Tumor (off-label) (must meet all)**:**

1. Diagnosis of inflammatory myofibroblastic tumor (a soft tissue sarcoma);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is ALK positive;
5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 450 mg (3 capsules) per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALK: anaplastic lymphoma kinase
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network
NSCLC: non-small cell lung cancer
ROS1: ROS proto-oncogene 1

Appendix *B: Therapeutic Alternatives*
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
ALK-positive NSCLC	450 mg PO once daily	450 mg/day

VI. Product Availability

Capsules: 150 mg

VII. References

1. Zykadia Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2017. Available at: www.zykadia.com. Accessed January 24, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed January 24, 2019.
3. National Comprehensive Cancer Network Guidelines. Non-Small Cell Lung Cancer Version 3.2019. Available at www.nccn.org. Accessed January 24, 2019.
4. National Comprehensive Cancer Network Guidelines. Central Nervous System Cancers Version 2.2018. Available at www.nccn.org. Accessed January 24, 2019.
5. National Comprehensive Cancer Network Guidelines. Soft Tissue Sarcoma Version 1.2019. Available at www.nccn.org. Accessed January 24, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.17.19	