Clinical Policy: Ceritinib (Zykadia)

Reference Number: ERX.SPA.05
Effective Date: 04.01.17
Last Review Date: 05.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Ceritinib (Zykadia®) is a 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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. Prescribed as a single agent;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 450 mg (3 capsules/tablets) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence)*.

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid – 6 months
Commercial – Length of Benefit

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. Prescribed as a single agent;
6. 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)*.*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:

Medicaid – 6 months
Commercial – Length of Benefit

C. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Zykadia for a covered indication and has received this medication for at least 30 days;
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/tablets) per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 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 QD	450 mg/day

VI. Product Availability
Capsule, tablet: 150 mg

VII. References

1. Zykadia Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2021. Available at: www.zykadia.com. Accessed February 14, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 14, 2022.
3. National Comprehensive Cancer Network Guidelines. Non-Small Cell Lung Cancer Version 1.2022. Available at www.nccn.org. Accessed February 14, 2022.
4. National Comprehensive Cancer Network Guidelines. Central Nervous System Cancers Version 2.2021. Available at www.nccn.org. Accessed February 14, 2022.
5. National Comprehensive Cancer Network Guidelines. Soft Tissue Sarcoma Version 3.2021. Available at www.nccn.org. Accessed February 14, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2018 annual review: no significant changes; specialist involvement in care added; dose changed from 750 to 450 mg per day per PI; approval durations increased to length of benefit; references updated.	02.13.18	05.18
2Q 2019 annual review: NCCN designation of advanced NSCLC added; NCCN recommended use for Zykadia as first-line therapy for ROS1 positive NSCLC added; references reviewed and updated.	02.19.19	05.19
New FDA-approved oral tablets added.	04.09.19	05.19
2Q 2020 annual review: no significant changes; added Medicaid line of business with 6/12 month initial/continued authorization duration; references reviewed and updated.	02.11.20	05.20
2Q 2021 annual review: no significant changes; references reviewed and updated.	01.12.21	05.21
2Q 2022 annual review: added criterion for Zykadia being prescribed as single-agent therapy for NSCLC and inflammatory myofibroblastic tumor indications per NCCN; references reviewed and updated.	02.14.22	05.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.