Applicable Drugs: Zykadia (ceritinib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 11/17/2025

Date Last Reviewed / Revised: 10/16/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met.)

I. Documentation the following FDA-approved diagnosis AND must meet all criteria listed under the applicable diagnosis:

II. FDA-Approved Indication(s)

A. Non-small cell lung cancer (NSCLC)

i. Documentation disease is anaplastic lymphoma kinase positive (ALK)-positive as detected by an FDA-approved test.

ii. Documentation of advanced or metastatic disease.

iii. Zykadia will be used as a single agent.

iv. Meets ONE of the following criteria (1 or 2):

1. Zykadia will be used as first line therapy.

2. Documentation the patient is intolerant to or has progressed on treatment with Xalkori (crizotinib).

v. Minimum age requirement: 18 years old or older

Other Uses With Supportive Evidence

B. Central nervous system cancers

C. Histiocytic neoplasms

D. Soft tissue sarcoma

E. T-Cell lymphomas

F. Uterine neoplasms

III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Tablets: 150 mg
- Maximum dose: 450 mg once daily
- Quantity limit: 90 tablets or capsules / 30-day supply

APPROVAL LENGTH

- **Authorization:** 1 year
- **Re-Authorization:** 1 year - An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of symptomatic systemic disease with multiple lesions.

APPENDIX

N/A

REFERENCES

1. Zykadia. Prescribing Information. Novartis Pharmaceuticals Corporation, 2021. Accessed October 15, 2026. www.novartis.com/us-en/novartis_us/files/zykadia.pdf
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer. Version 9.2026. Updated September 22, 2026. Accessed October 15, 2026. www.nccn.org/professionals/physician_gls/pdf/nscl.pdf
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Central Nervous System Cancers. Version 3.2026. Updated August 17, 2026. Accessed October 15, 2026. www.nccn.org/professionals/physician_gls/pdf/cns.pdf
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Histiocytic Neoplasms. Version 4.2026. Updated September 16, 2026. Accessed October 15, 2026. www.nccn.org/professionals/physician_gls/pdf/histiocytic_neoplasms.pdf

5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Soft Tissue Sarcoma. Version 5.2026. Updated July 23, 2026. Accessed October 15, 2026. www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf
6. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. T-Cell Lymphomas. Version 2.2026. Updated February 13, 2026. Accessed October 15, 2026. www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf
7. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Uterine Neoplasms. Version 3.2026. Updated June 16, 2026. Accessed October 15, 2026. www.nccn.org/professionals/physician_gls/pdf/uterine.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.