Generic Name: ceritinib

Therapeutic Class or Brand Name: Zykadia

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 11/17/2025

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

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

I. Documentation the following diagnoses 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 clinical practice guidelines.

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 September 5, 2025. www.novartis.com/us-en/novartis_us/files/zykadia.pdf
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3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Central Nervous System Cancers. Version 2.2025. Updated August 28, 2025. Accessed September 18, 2025. www.nccn.org/professionals/physician_gls/pdf/cns.pdf
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Histiocytic Neoplasms. Version 1.2025. Updated June 20, 2025. Accessed September 18, 2025. www.nccn.org/professionals/physician_gls/pdf/histiocytic_neoplasms.pdf
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Soft Tissue Sarcoma. Version 1.2025. Updated May 2, 2025. Accessed September 18, 2025. www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf

6. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. T-Cell Lymphomas. Version 2.2025. Updated May 28, 2025. Accessed September 18, 2025. www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf
7. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Uterine Neoplasms. Version 3.2025. Updated March 7, 2025. Accessed September 18, 2025. www.nccn.org/professionals/physician_gls/pdf/uterine.pdf