



PRIOR AUTHORIZATION POLICY

- POLICY:** Oncology (Oral – Anaplastic Lymphoma Kinase [ALK]-Positive Agent) – Zykadia Prior Authorization Policy
- Zykadia® (ceritinib capsules and tablets – Novartis)

REVIEW DATE: 06/17/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Zykadia, a kinase inhibitor, is indicated for the treatment of metastatic **non-small cell lung cancer** (NSCLC) in adults whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.¹

GUIDELINES

Zykadia is addressed in National Comprehensive Cancer Network (NCCN) guidelines:²⁻⁵

- **Histiocytic Neoplasms:** Guidelines (version 1.2026 – May 8, 2026) recommend Zykadia as a "Useful in Certain Circumstances" treatment option for ALK-positive Erdheim-Chester Disease (category 2A).³
- **Inflammatory Myofibroblastic Tumor (IMT):** NCCN Soft Tissue Sarcoma guidelines (version 3.2026 – March 12, 2026) recommend Zykadia as a "Preferred" treatment option for IMT with ALK translocation (category 2A).

The NCCN Uterine Neoplasms guidelines (version 2.2026 – November 14, 2025) recommend Zykadia as “Useful in Certain Circumstances” for first-line therapy for advanced, recurrent/metastatic, or inoperable IMT with *ALK* translocation (category 2A) for uterine sarcoma. ^{5,6}

- **NSCLC:** Guidelines (version 6.2026 – June 12, 2026) recommend testing for biomarkers (e.g., *ALK* rearrangement, *ROS* proto-oncogene 1 (*ROS1*) gene rearrangement) in eligible patients with NSCLC.⁴
 - *ALK* rearrangement-positive NSCLC: If *ALK* rearrangement is discovered prior to first-line systemic therapy, Zykadia is listed under “Useful in Certain Circumstances” (category 1). If *ALK* rearrangement is discovered during first-line systemic therapy, interrupt current therapy and treat with Zykadia (category 2A) or one of the other “Preferred” first-line therapies. NCCN recommendations for patients with disease progression often include continuing the first-line targeted therapy, depending on type of progression. Zykadia is no longer recommended in guidelines for *ROS1* rearrangement-positive NSCLC.
- **T-Cell Lymphomas:** Guidelines (version 2.2026 – February 13, 2026) recommend Zykadia for *ALK*-positive anaplastic large-cell lymphoma (ALCL) under “Other Recommended Regimens” (category 2A) for initial palliative-intent therapy and for second-line/subsequent therapy (regardless of intention to transplant).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Zykadia. All approvals are provided for the duration noted below.

Zykadia® (ceritinib capsules and tablets - Novartis) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

- 1. Non-Small Cell Lung Cancer (NSCLC) – Anaplastic Lymphoma Kinase (ALK)-Positive.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
 - A)** Patient is ≥ 18 years of age; AND
 - B)** Patient has advanced or metastatic disease; AND
 - C)** Patient has anaplastic lymphoma kinase (*ALK*)-positive disease.

Other Uses with Supportive Evidence

- 2. Erdheim-Chester Disease.** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A)** Patient is ≥ 18 years of age; AND

B) Patient has anaplastic lymphoma kinase (*ALK*) rearrangement/fusion-positive disease.

3. Inflammatory Myofibroblastic Tumor. Approve for 1 year if the patients meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) Patient has anaplastic lymphoma kinase (*ALK*)-positive disease; AND

C) Patient meets ONE of the following (i or ii):

i. Patient has advanced, recurrent, or metastatic disease; OR

ii. The tumor is inoperable.

4. Peripheral T-Cell Lymphomas. Approve for 1 year if the patient meets BOTH of the following (A and B):

A) Patient is ≥ 18 years of age; AND

B) Patient has anaplastic lymphoma kinase (*ALK*)-positive anaplastic large cell lymphoma (ALCL).

CONDITIONS NOT COVERED

Zykadia® (ceritinib capsules and tablets - Novartis) is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Zykadia® capsules and tablets [prescribing information]. East Hanover, NJ: Novartis; October 2021.
2. The NCCN Drugs & Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on June 15, 2026. Search terms: ceritinib.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 1.2026 – May 8, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on June 15, 2026.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 6.2026 – June 12, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on June 15, 2026.
5. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 3.2026 – March 12, 2026). ©2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on June 15, 2026.
6. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2026 – November 14, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on June 15, 2026.
7. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 2.2026 – February 13, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on June 15, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Peripheral T-Cell Lymphomas: Added new approval condition and criterion under "Other Uses with Supportive Evidence".	08/07/2024

Update	04/21/2025: The policy name was changed from "Oncology – Zykadia PA Policy" to "Oncology (Oral – Anaplastic Lymphoma Kinase [ALK]-Positive Agent) – Zykadia PA Policy".	N/A
Annual Revision	Non-Small Cell Lung Cancer with ROS1 Rearrangement: Removed this condition of approval from "Other Uses with Supportive Evidence".	07/30/2025
Annual Revision	Non-Small Cell Lung Cancer (NSCLC) – Anaplastic Lymphoma Kinase (ALK)-Positive: In reference to ALK-positive disease, the requirement that the mutation was detected by an approved test was removed.	06/17/2026

N/A – Not applicable.

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