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5.21.046

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	June 27, 2014
Subject:	Zykadia	**Page:**	1 of 5

Last Review Date: December 13, 2024

Zykadia

Description

Zykadia (ceritinib)

Background
Zykadia (ceritinib) is used in patients with a certain type of late-stage (metastatic) non-small cell lung cancer (NSCLC), which is caused by a defect in a gene called anaplastic lymphoma kinase (ALK). Zykadia is a tyrosine kinase inhibitor that blocks proteins that promote the development of cancerous cells. It is intended for patients with metastatic ALK-positive NSCLC (1).

Regulatory Status
FDA-approved indication: Zykadia is a kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test (1).

Off-Label Uses: (2-3)

1. Inflammatory Myofibroblastic Tumor (IMT) with ALK translocation

Zykadia can cause hepatotoxicity therefore liver function tests including AST, ALT and total bilirubin should be monitored at least monthly. Zykadia can cause interstitial lung disease (ILD) or pneumonitis. Zykadia should be permanently discontinued in patients diagnosed with treatment-related ILD/pneumonitis. Zykadia can cause QTc interval prolongation, which requires monitoring of electrocardiograms and electrolytes in patients with congestive heart failure (1).

Zykadia can cause fetal harm when administered to a pregnant woman. The limited available data on the use of Zykadia in pregnant women are insufficient to inform a risk (1).

Safety and effectiveness of Zykadia in pediatric patients have not been established (1).

Related policies
Alecensa, Alunbrig, Lorbrena, Xalkori

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Zykadia may be considered **medically necessary** if the conditions indicated below are met.

Zykadia may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Metastatic non-small cell lung cancer (NSCLC)
2. Inflammatory Myofibroblastic Tumor (IMT)

AND ALL of the following:

a. Anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test
b. Prescriber agrees to monitor liver function tests including ALT, AST, and total bilirubin monthly

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Metastatic non-small cell lung cancer (NSCLC)
2. Inflammatory Myofibroblastic Tumor (IMT)

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor liver function tests including ALT, AST, and total bilirubin monthly

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 252 units per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Zykadia (ceritinib) is an anaplastic lymphoma kinase (ALK) tyrosine kinase inhibitor that blocks proteins that promote the development of cancerous cells. It is intended for patients with metastatic ALK-positive NSCLC. Safety and effectiveness of Zykadia in patients under 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Zykadia while maintaining optimal therapeutic outcomes.

References

1. Zykadia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; October 2021.
2. NCCN Drugs & Biologics Compendium®. Ceritinib 2024. National Comprehensive Cancer Network, Inc. Accessed on October 29, 2024.
3. NCCN Clinical Practice Guidelines in Oncology® Soft Tissue Sarcoma (Version 3.2024). National Comprehensive Cancer Network, Inc. September 2024. Accessed on October 29, 2024.

Policy History

Date	Action
June 2014	New addition to PA
September 2014	Annual review
December 2015	Annual editorial review and reference update
June 2016	Annual editorial review and reference update Policy code changed from 5.04.46 to 5.21.46
June 2017	Reference update; Removal of disease progression or intolerance to Xalkori in initiation criteria; Addition of metastatic disease requirement to initiation and continuation criteria; Addition of no disease progression or unacceptable toxicity to continuation criteria; Addition of Inflammatory Myofibroblastic Tumor (IMT)
September 2017	Annual editorial review Addition of quantity limits
June 2018	Annual editorial review and reference update
March 2019	Annual review and reference update
June 2019	Revised quantity limits to reflect availability of Zykadia tablets and the new dosing of 450 mg daily
September 2019	Annual review and reference update
June 2020	Annual review and reference update
December 2021	Annual review and reference update
March 2022	Annual editorial review and reference update
December 2023	Annual editorial review and reference update. Removed continuation requirement of ALK-positive. Reworded requirement to monitor LFTs. Changed policy number to 5.21.046
March 2024	Annual review and reference update
December 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.