



RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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).



**BlueCross.
BlueShield.**

Federal Employee Program.

ZYKADIA (ceritinib)

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 2025. National Comprehensive Cancer Network, Inc. Accessed on January 14, 2025.
3. NCCN Clinical Practice Guidelines in Oncology® Soft Tissue Sarcoma (Version 4.2024). National Comprehensive Cancer Network, Inc. November 2024. Accessed on January 14, 2025.