Zykadia

Description

Zykadia (ceritinib)

Background

Zykadia 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 is pregnancy category D and may cause fetal harm when administered to a pregnant woman (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 in patients 18 years of age and older for the treatment of metastatic, anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) when the conditions indicated below are met.

Zykadia is considered investigational for patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

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. Agreement of prescriber to monitor liver function tests including ALT, AST and total bilirubin monthly

Prior – Approval Renewal Requirements
Section: Prescription Drugs  
Subsection: Antineoplastic Agents  
Subject: Zykadia  
Effective Date: October 1, 2019  
Original Policy Date: June 27, 2014  
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Age  
18 years of age or older

Diagnosis

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
   b. Agreement of prescriber to monitor liver function tests including ALT, AST and total bilirubin monthly
   c. NO disease progression or unacceptable toxicity

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

Summary
Zykadia 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


## Policy History

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<td>June 2014</td>
<td>New addition to PA</td>
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<tr>
<td>September 2014</td>
<td>Annual review</td>
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<tr>
<td>December 2015</td>
<td>Annual editorial review and reference update</td>
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<td>June 2016</td>
<td>Annual editorial review and reference update; Policy code changed from 5.04.46 to 5.21.46</td>
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<tr>
<td>June 2017</td>
<td>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)</td>
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<td>June 2018</td>
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<tr>
<td>March 2019</td>
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<tr>
<td>June 2019</td>
<td>Revised quantity limits to reflect availability of Zykadia tablets and the new dosing of 450 mg daily</td>
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## Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.