

# Inhaled Cystic Fibrosis Criteria

Revised 09/17/2024

## ANTIBIOTICS – INHALED

<b>Length of Authorization:</b> Initial – 6 months	
Renewal – 1 year	
<b>PREFERRED: PA REQUIRED</b>	<b>NON-PREFERRED: PA REQUIRED</b>
tobramycin inhalation pak/solution (generic for Tobi®)	Arikayce® Vial – see drug specific adult criteria below
Tobi® Podhaler® age ≥ 6	Bethkis® Ampule
	Cayston® Solution
	Kitabis™ Pak
	Tobi® Solution

## CHILDREN – CRITERIA TO APPROVE

**All** the following:

- Diagnosis of Cystic Fibrosis (CF) with pseudomonas aeruginosa of the airway (culture **must** be documented)
- Prescriber is a pulmonologist, infectious disease specialist, or expert in treatment of cystic fibrosis or consult notes are provided.
- For TOBI Podhaler: inadequate response, adverse reaction, or contraindication with tobramycin inhalation pak or solution (generic for Tobi)
- For Cayston: inadequate response, adverse reaction, or contraindication with **one** preferred agent
- For Bethkis, Kitabis, and Tobi solution: inadequate response, adverse reaction, or contraindication with **two** preferred agents
- If tobramycin is prescribed concurrently (or for alternating use) with Cayston, documentation supports inadequate response to either agent alone (e.g., deteriorating pulmonary status, recurrent pulmonary exacerbations)

## ADULTS – CRITERIA TO APPROVE

**All** the following:

- Diagnosis of Cystic Fibrosis (CF) with pseudomonas aeruginosa of the airway (culture **must** be documented)
- Prescriber is a pulmonologist, infectious disease specialist, or expert in treatment of cystic fibrosis or consult notes are provided.
- For TOBI Podhaler: inadequate response, adverse reaction, or contraindication with tobramycin inhalation pak or solution (generic for Tobi)
- For Cayston: inadequate response, adverse reaction, or contraindication with **one** preferred agent
- For Bethkis, Kitabis, and Tobi solution: inadequate response, adverse reaction, or contraindication with **two** preferred agents

- If tobramycin is prescribed concurrently (or for alternating use) with Cayston, documentation supports inadequate response to either agent alone (e.g., deteriorating pulmonary status, recurrent pulmonary exacerbations)

**Arikayce:**

- Age ≥ 18 years
- Diagnosis of confirmed refractory Mycobacterium avium complex (MAC) lung disease.
- Patient has failed to achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug treatment regimen (laboratory documentation required)
- Arikayce will be part of a combination antibacterial drug regimen.
- Prescriber is a pulmonologist, infectious disease specialist, or expert in treatment of cystic fibrosis or consult notes are provided.

## RENEWAL CRITERIA

**All** the following:

- Patient has met all initial criteria.
- Patient is responding well to therapy.
- Patient has not experienced any treatment-restricting adverse effects.

## REVISION HISTORY

Date	Issues/Updates
09/17/2024	• Initial draft creation

Orange Text = Emphasis    Blue Text = Hyperlinks    Red Text = New Info    Green Text = Auto PA