

Inhaled Cystic Fibrosis Criteria

Revised 06/28/2024

ANTIBIOTICS, INHALED

Length of Authorization: Initial – 6 months	
Renewal – 1 year	
PREFERRED – PA REQUIRED	NON-PREFERRED – PA REQUIRED
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.

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

REVISION HISTORY

Date	Issues/Updates
06/28/2024	<ul style="list-style-type: none">Initial draft creation

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