

## Texas Prior Authorization Program Clinical Criteria

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### Drug/Drug Class

## Inhaled Antibiotics

*This criteria was recommended for review by an MCO to ensure appropriate and safe utilization*

### Clinical Criteria Information Included in this Document

#### Inhaled Antibiotics

- **Drugs requiring clinical prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Clinical prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes)
- **References:** clinical publications and sources relevant to this clinical criteria

**Note:** Click the hyperlink to navigate directly to that section.

### Revision Notes

- Annual review by staff
- Updated references



## Inhaled Antibiotics

### Drugs Requiring Clinical Prior Authorization

The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit [TxVendorDrug.com/formulary/formulary-search](http://TxVendorDrug.com/formulary/formulary-search).

Label Name	GCN
BETHKIS 300 MG/4 ML AMPULE	16122
CAYSTON 75 MG INHAL SOLUTION	28039
KITABIS PAK 300 MG/5 ML	37569
TOBI 300 MG/ 5 ML SOLUTION	61551
TOBI PODHALER 28 MG INHALE CAP	30025
TOBRAMYCIN 300 MG/5 ML AMPULE	61551



## Inhaled Antibiotics

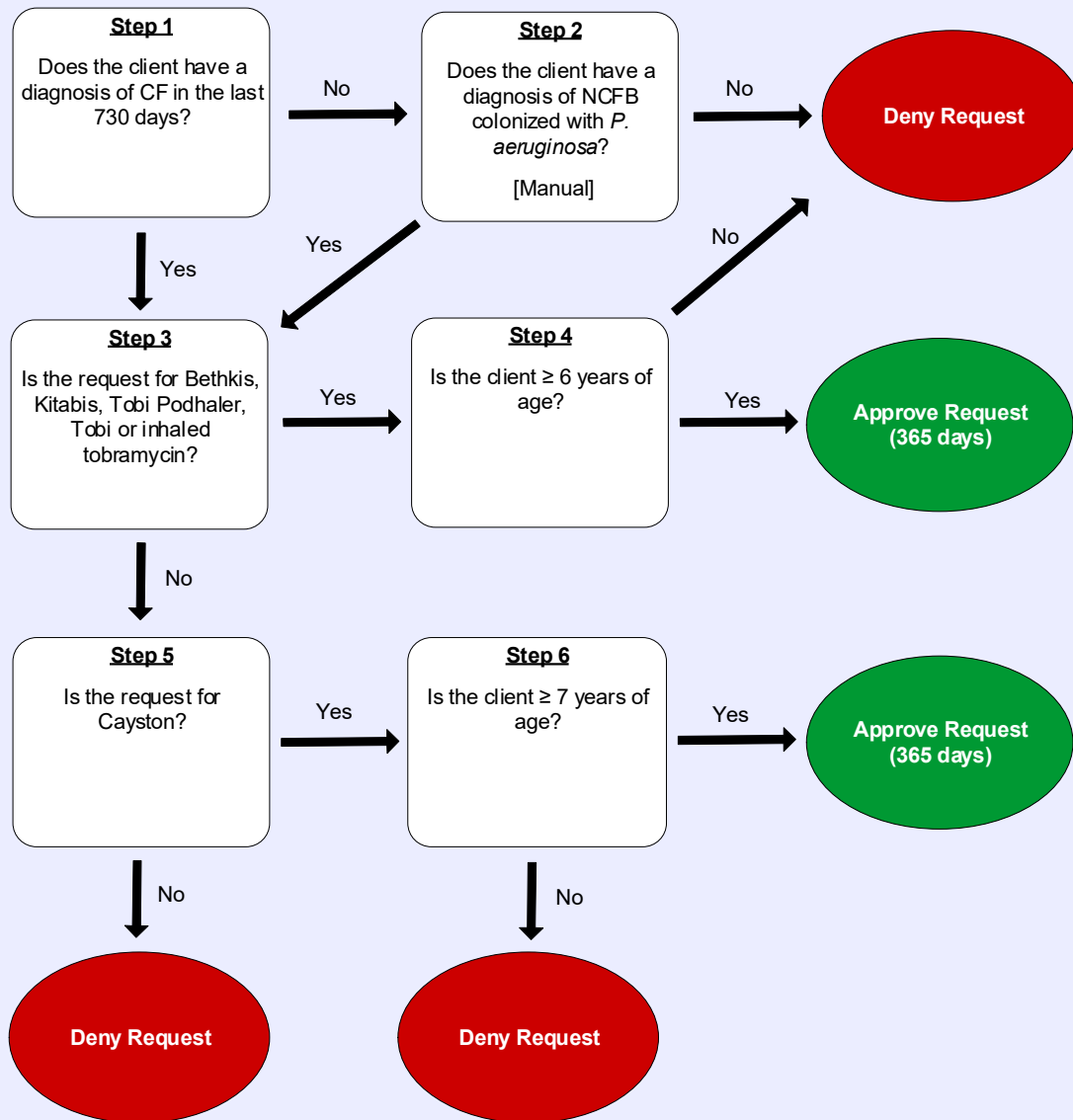
### Clinical Criteria Logic

1. Does the client have a **diagnosis of cystic fibrosis** in the last 730 days?  
 Yes – Go to #3  
 No – Go to #2
2. Does the client have a diagnosis of non-cystic fibrosis bronchiectasis (NCFB) colonized with *Pseudomonas aeruginosa*? [Manual]  
 Yes – Go to #3  
 No – Deny
3. Is the request for Bethkis, Kitabis, Tobi, Tobi Podhaler or inhaled tobramycin?  
 Yes – Go to #4  
 No – Go to #5
4. Is the client greater than or equal to ( $\geq$ ) 6 years of age?  
 Yes – Approve (365 days)  
 No – Deny
5. Is the request for Cayston?  
 Yes – Go to #6  
 No – Deny
6. Is the client greater than or equal to ( $\geq$ ) 7 years of age?  
 Yes – Approve (365 days)  
 No – Deny



# Inhaled Antibiotics

## Clinical Criteria Logic Diagram





## Inhaled Antibiotics

### Clinical Criteria Supporting Tables

<b>Step 1 (diagnosis of cystic fibrosis)</b> <b>Required quantity: 1</b> <b>Look back timeframe: 730 days</b>	
<b>ICD-10 Code</b>	<b>Description</b>
E8411	CYSTIC FIBROSIS WITH INTESTINAL MANIFESTATIONS, MECONIUM ILEUS IN CF
E8419	CYSTIC FIBROSIS WITH OTHER INTESTINAL MANIFESTATIONS
E848	CYSTIC FIBROSIS WITH OTHER MANIFESTATIONS
E840	CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS
E849	CYSTIC FIBROSIS, UNSPECIFIED



## Inhaled Antibiotics

### Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier / Gold Standard, Inc. 2023. Available at [www.clinicalpharmacology.com](http://www.clinicalpharmacology.com). Accessed on August 15, 2023.
2. Drug Facts and Comparisons. eFacts [online]. 2023. Available from Wolters Kluwer Health, Inc. Accessed on August 15, 2023.
3. Bethkis Prescribing Information. Woodstock, IL: Chiesi USA Inc; February 2023.
4. Cayston Prescribing Information. Foster City, CA. Gilead Sciences, Inc. February 2019.
5. Kitabis Prescribing Information. Midlothian, VA. PARI. August 2021.
6. Tobi Podhaler Prescribing Information. San Carlos, CA. Mylan Pharmaceuticals Inc. February 2023.
7. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Prevention and Eradication of Initial Pseudomonas aeruginosa Infection Clinical Care Guidelines: Executive Summary. *Ann Am Thorac Soc*. 2014;11(10):1640-50.
8. Castellani C, Duff AJ, Bell SC, et al. ECFS best practice guidelines: the 2018 revision. *Journal of Cystic Fibrosis* 2018;17:153-178.
9. Hill AT, Sullivan AL, Chalmers JD, et al. British Thoracic Society Bronchiectasis in Adults Guideline Development Group. British Thoracic Society Guideline for Bronchiectasis in Adults. *Thorax* 2019;74(1):1-69.
10. Kalil AC, Metersky ML, Klompas M, et al. Management of Adults with Hospital-acquired and Ventilator-associated Pneumonia: 2016 Clinical Practice Guidelines by the Infectious Diseases Society of America and the American Thoracic Society. *Clin Inf Diseases* 2016;63(5):61-111.
11. Siddhartha GK, Dimango E, Hadjiliadis D, et al. Cystic Fibrosis Foundation Consensus Guidelines for the Care of Individuals with Advanced Cystic Fibrosis Lung Disease. *Journal of Cystic Fibrosis* 2020; 19: 344-354.



## Inhaled Antibiotics

### Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
04/26/2019	Initial publication and presentation to the DUR Board
01/24/2020	Presentation to the DUR Board – request addition of non-cystic fibrosis bronchiectasis colonized with <i>Pseudomonas aeruginosa</i> to the diagnosis table
02/13/2020	Added diagnosis of NCFB colonized with <i>Pseudomonas aeruginosa</i> to the logic and logic diagram
04/15/2021	Annual review by staff Updated references
10/28/2022	Annual review by staff Updated references
10/31/2023	Annual review by staff Updated references