

Texas Prior Authorization Program
Clinical Criteria

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

- [Drugs requiring prior authorization](#): the list of drugs requiring prior authorization for this clinical criteria
- [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); provided when applicable
- [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



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Drugs Requiring Prior Authorization

The listed GCNs may not be an indication of Texas Medicaid Formulary coverage. To learn the current formulary coverage, visit txvendordrug.com/formulary/formulary-search.

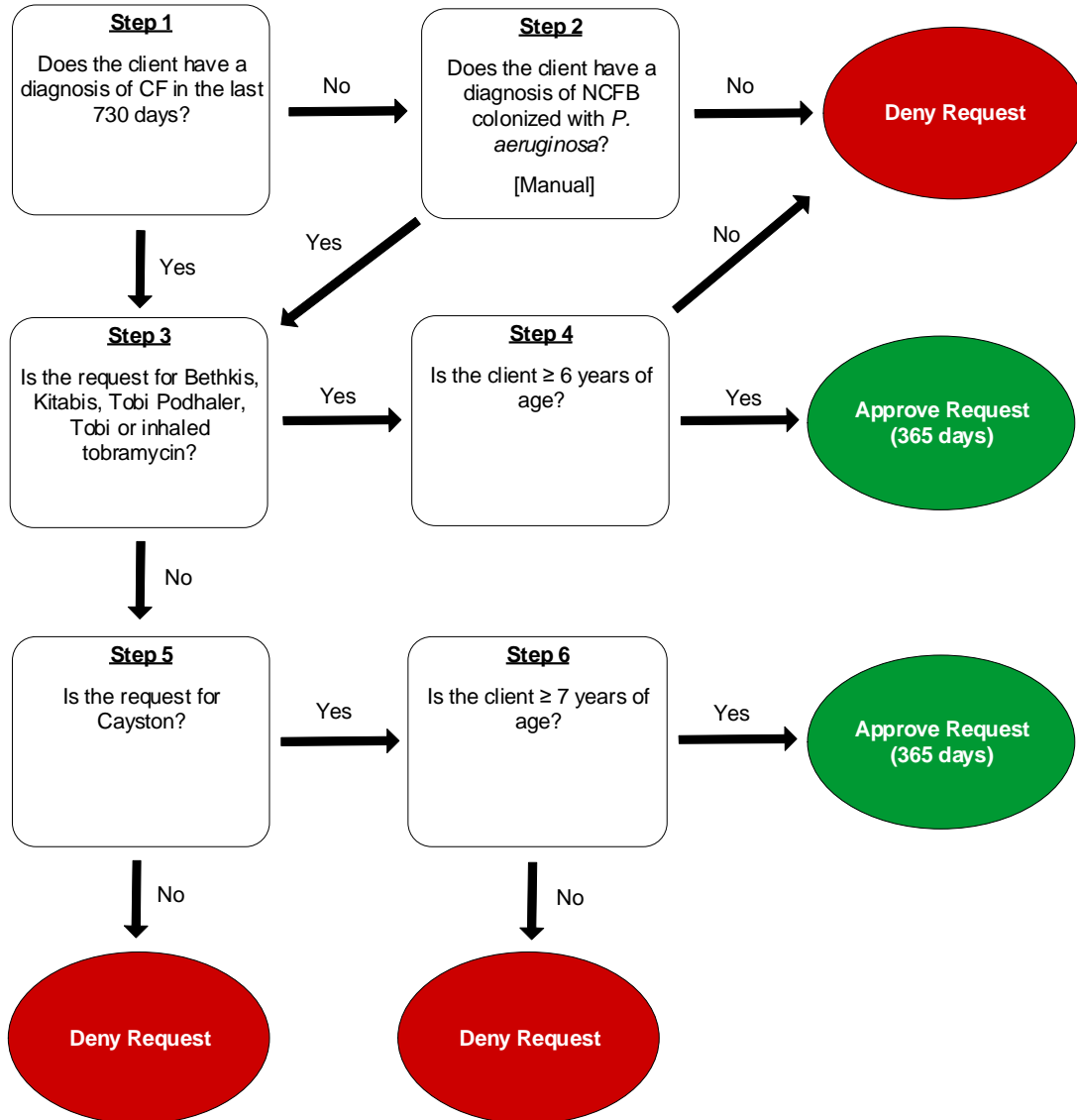
Drugs Requiring Prior Authorization	
Label Name	GCN
BETHKIS 300 MG/4 ML AMPULE	16122
CAYSTON 75 MG INHAL SOLUTION	28039
KITABIS PAK 300 MG/5 ML	37569
TOBI 300 MG/ 5 ML SOLUTION	61551
TOBI PODHALER 28 MG INHALE CAP	30025
TOBRAMYCIN 300 MG/5 ML AMPULE	61551
TOBRAMYCIN 300 MG/4 ML AMPULE	16122

**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 Podhaler, Tobi, 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





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Clinical Criteria Supporting Tables

Table 1 (diagnosis of cystic fibrosis) Required quantity: 1 Look back timeframe: 730 days	
ICD-10 Code	Description
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



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Clinical Criteria References

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2. Drug Facts and Comparisons. eFacts [online]. 2025. Available at www.factsandcomparisons.com. Accessed on February 5, 2025.
3. Bethkis Prescribing Information. Woodstock, IL: Chiesi USA Inc; February 2023.
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5. Kitabis Prescribing Information. Midlothian, VA. PARI. December 2024.
6. Tobi Podhaler Prescribing Information. San Carlos, CA. Viatris Specialty LLC. 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.
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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.
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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	<ul style="list-style-type: none"> Initial publication and presentation to the DUR Board
01/24/2020	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Added diagnosis of NCFB colonized with <i>Pseudomonas aeruginosa</i> to the logic and logic diagram
04/15/2021	<ul style="list-style-type: none"> Annual review by staff Updated references
10/28/2022	<ul style="list-style-type: none"> Annual review by staff Updated references
10/31/2023	<ul style="list-style-type: none"> Annual review by staff Updated references
06/30/2024	<ul style="list-style-type: none"> Annual review by staff Added GCN for tobramycin 300mg/4mL ampule (16122) Updated references
02/28/2025	<ul style="list-style-type: none"> Annual review by staff Updated references