

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

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

- Initial publication



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.

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

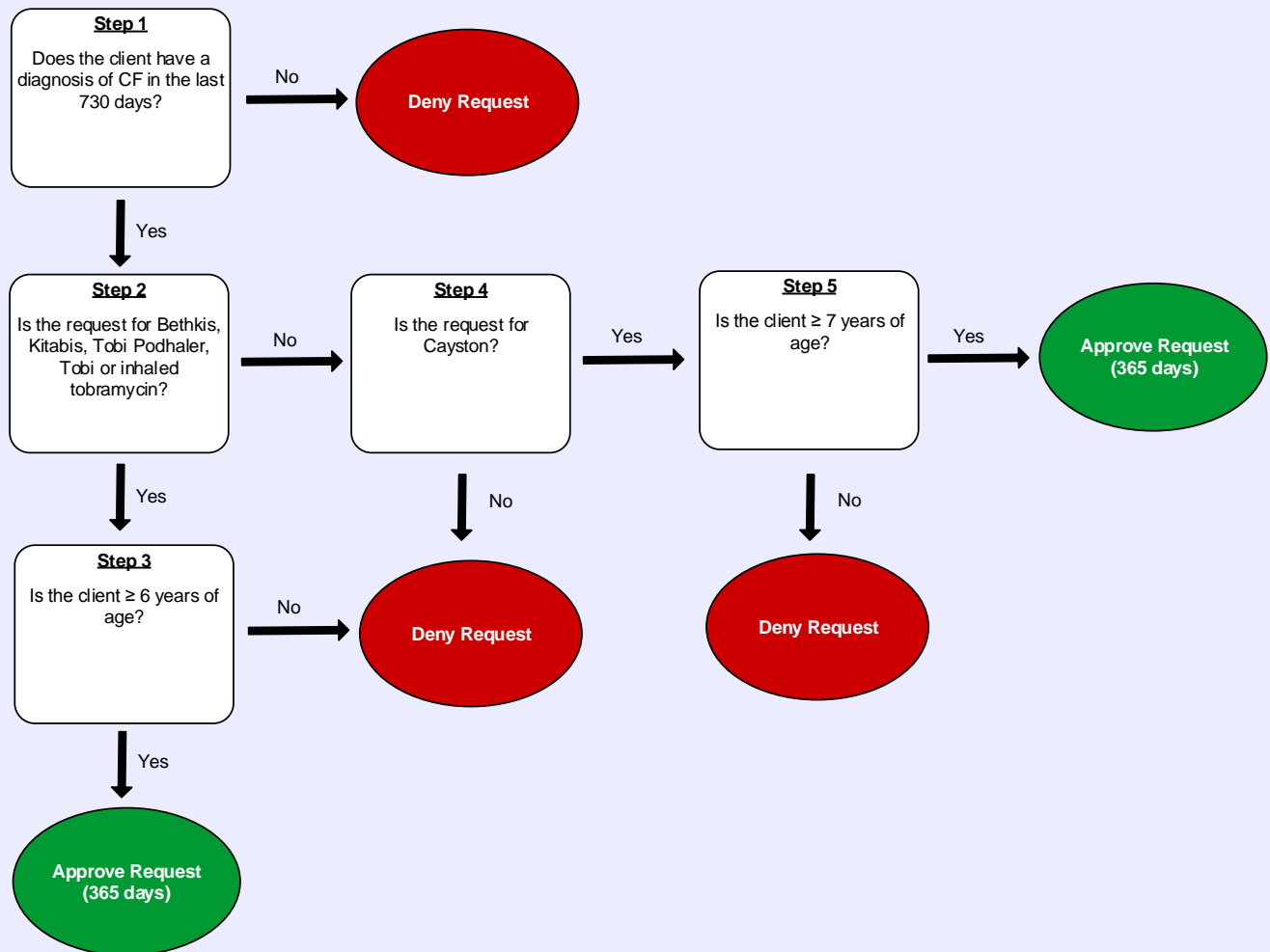
Clinical Criteria Logic

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

Step 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



Inhaled Antibiotics

Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier / Gold Standard, Inc. 2019. Available at www.clinicalpharmacology.com. Accessed on April 26, 2019.
2. Drug Facts and Comparisons. eFacts [online]. 2019. Available from Wolters Kluwer Health, Inc. Accessed on April 26, 2019.
3. Bethkis Prescribing Information. Woodstock, IL. Cornerstone Therapeutics, Inc. October 2013.
4. Cayston Prescribing Information. Foster City, CA. Gilead Sciences, Inc. February 2019.
5. Kitabis Prescribing Information. Midlothian, VA. PARI. May 2016.
6. Tobi Podhaler Prescribing Information. East Hanover, NJ. Novartis Pharmaceuticals Corporation. October 2015.
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.



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