

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

- Added diagnosis of non-cystic fibrosis bronchiectasis (NCFB) colonized with *Pseudomonas aeruginosa* to logic and logic diagram



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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 |



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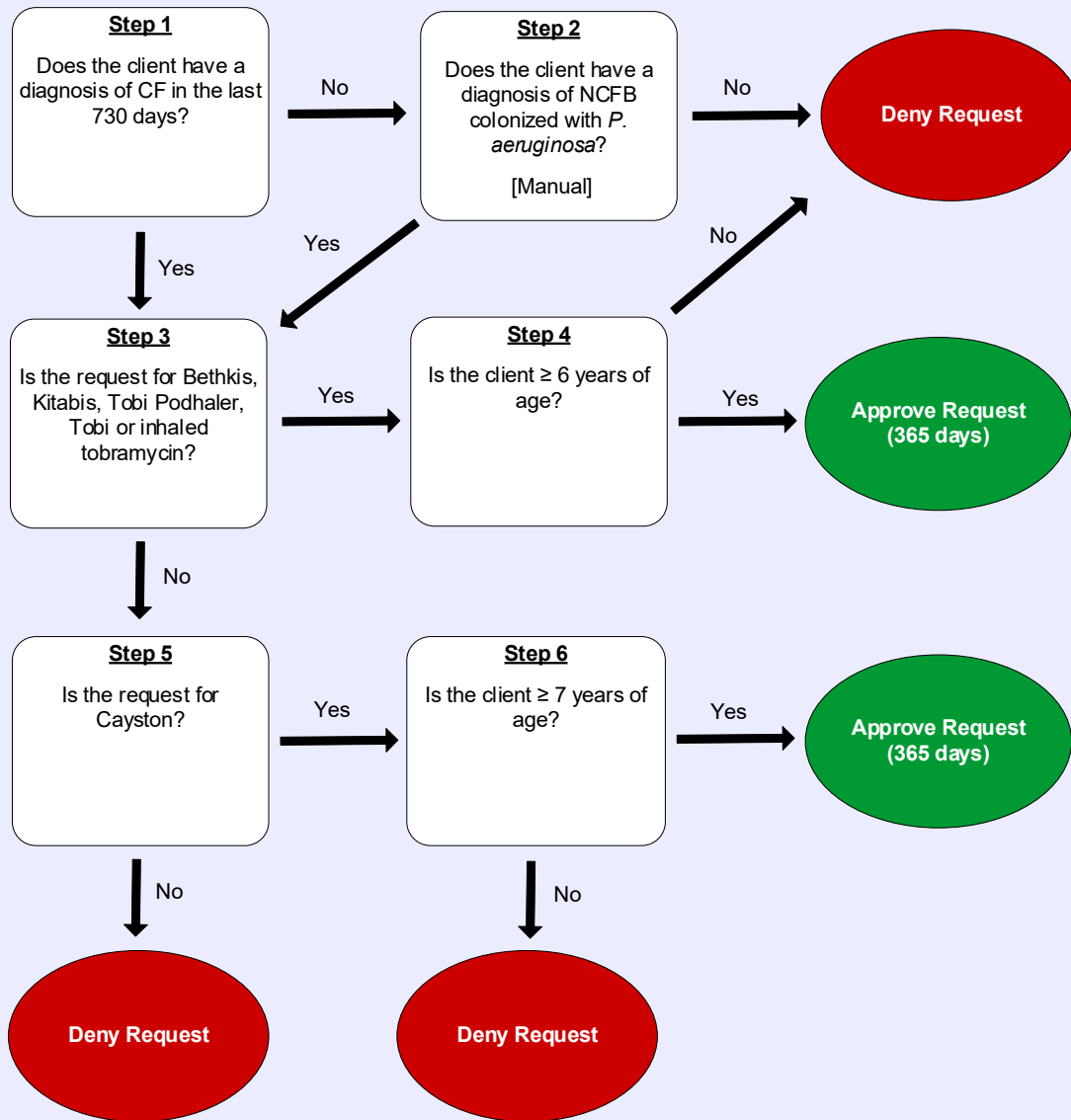
Clinical Criteria Logic

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



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Clinical Criteria Logic Diagram





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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 |



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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.
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.



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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 | 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 |