Texas Prior Authorization Program
Clinical Criteria

Drug/Drug Class

Arikayce (Amikacin)

This criteria was recommended for review by the Texas Medicaid Vendor Drug Program to ensure appropriate and safe utilization.

Clinical Criteria Information included in this Document

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- 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**
ARIKAYCE 590 MG/8.4 ML VIAL	45435

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Clinical Criteria Logic

1. Is the client greater than or equal to (≥) 18 years of age?

   [ ] Yes – Go to #2

   [ ] No – Deny

2. Does the client have a diagnosis of *Mycobacterium avium* complex (MAC) lung disease in the last 730 days?

   [ ] Yes – Go to #3

   [ ] No – Deny

3. Has the client had therapy with at least two of the drugs listed for at least 180 days in the last 365 days prior to requesting therapy with Arikayce?

   [ ] Yes – Go to #4

   [ ] No – Deny

4. Is Arikayce being prescribed concurrently with at least 2 of the drugs listed?

   [ ] Yes – Approve (365 days)

   [ ] No – Deny

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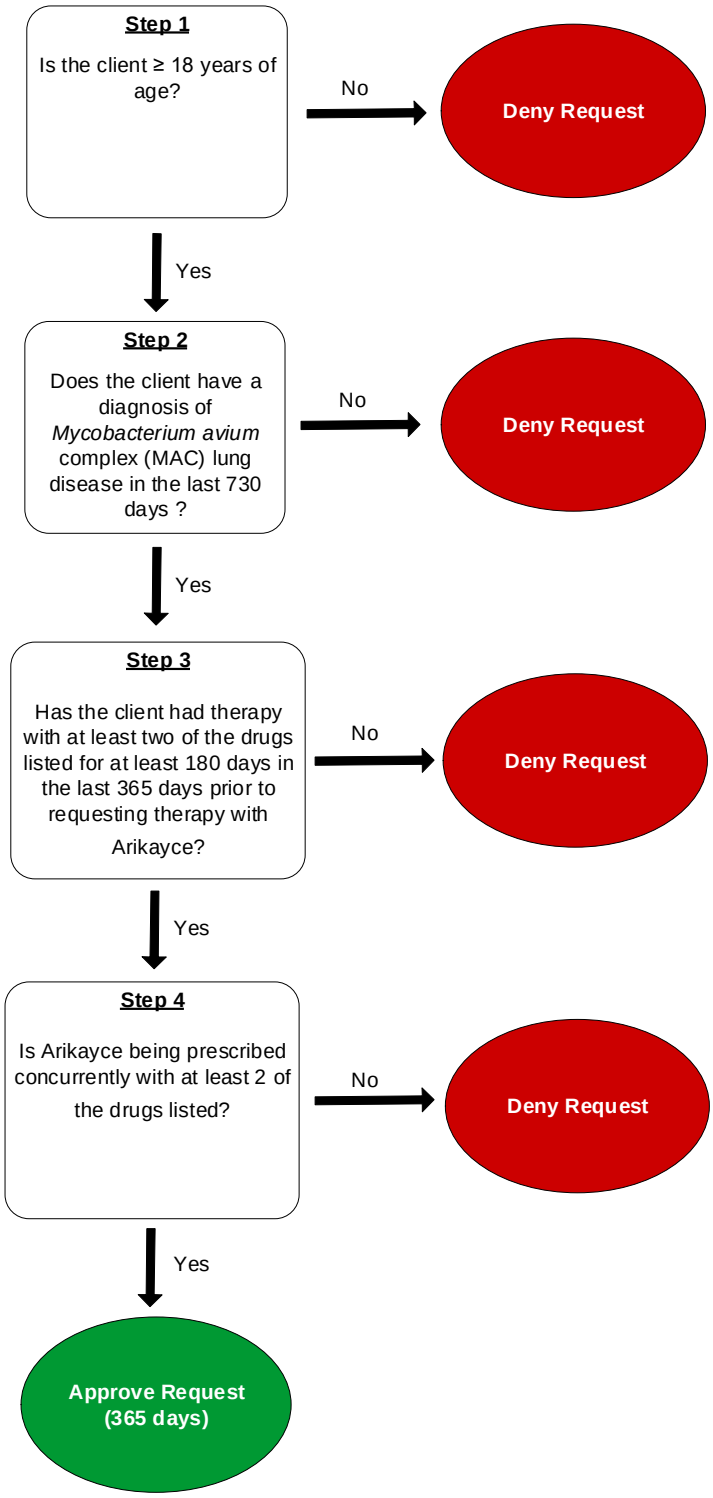
Clinical Criteria Logic Diagram



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Clinical Criteria Supporting Tables

Table 2 (diagnosis of *Mycobacterium avium* complex (MAC) lung disease) Required quantity: *1* Look back timeframe: *730* days	
ICD-10 Code	**Description**
A310	PULMONARY MYCOBACTERIAL INFECTION
A312	DISSEMINATED MYCOBACTERIUM AVIUM – INTRACELLULARE COMPLEX (DMAC)

Table 3 (claims for drugs recommended as prior multi-drug therapy) Required quantity: *2 (180 days total therapy)* Look back timeframe: *365* days	
GCN	**Description**
48792	AZITHROMYCIN 100 MG/5 ML SUSP
61199	AZITHROMYCIN 200 MG/5 ML SUSP
48793	AZITHROMYCIN 250 MG TABLET
61198	AZITHROMYCIN 500 MG TABLET
48794	AZITHROMYCIN 600 MG TABLET
48795	AZITHROMYCIN I.V. 500 MG VIAL
48790	AZITHROMYCIN 1 GM PWD PACKET
43532	BAXDELA 450 MG TABLET
47050	CIPRO 250 MG TABLET
47051	CIPRO 500 MG TABLET
47056	CIPROFLOXACIN 250 MG/5 ML
47057	CIPROFLOXACIN 500 MG/5 ML
47053	CIPROFLOXACIN HCL 100 MG TAB

Table 3 (claims for drugs recommended as prior multi-drug therapy) **Required quantity: *2 (180 days total therapy)*** **Look back timeframe: *365* days**	
GCN	**Description**
47050	CIPROFLOXACIN HCL 250 MG TAB
47051	CIPROFLOXACIN HCL 500 MG TAB
47052	CIPROFLOXACIN HCL 750 MG TAB
52121	CIPROFLOXACIN 200 MG/100 ML – D5W
52122	CIPROFLOXACIN 400 MG/100 ML – D5W
11670	CLARITHROMYCIN 125 MG/5 ML SUSPENSION
48852	CLARITHROMYCIN 250 MG TABLET
11671	CLARITHROMYCIN 250 MG/5 ML SUSPENSION
48851	CLARITHROMYCIN 500 MG TABLET
48850	CLARITHROMYCIN ER 500 MG TABLET
41800	ETHAMBUTOL HCL 100 MG TABLET
41801	ETHAMBUTOL HCL 400 MG TABLET
41741	ISONIAZID 100 MG TABLET
41742	ISONIAZID 300 MG TABLET
41730	ISONIAZID 50 MG/5 ML
23725	LEVOFLOXACIN 25 MG/ML SOLUTION
47073	LEVOFLOXACIN 250 MG TABLET
47074	LEVOFLOXACIN 500 MG TABLET
89597	LEVOFLOXACIN 750 MG TABLET
89596	LEVOFLOXACIN 750 MG/150 ML-D5W
47075	LEVOFLOXACIN 500 MG/100 ML-D5W
47072	LEVOFLOXACIN 250 MG/50 ML-D5W
50767	MOXIFLOXACIN HCL 400 MG TABLET

Table 3 (claims for drugs recommended as prior multi-drug therapy) **Required quantity: *2 (180 days total therapy)*** **Look back timeframe: *365* days**	
GCN	**Description**
29810	MYCOBUTIN 150 MG CAPSULE
29810	RIFABUTIN 150 MG CAPSULE
41260	RIFAMPIN 150 MG CAPSULE
41261	RIFAMPIN 300 MG CAPSULE
48792	ZITHROMAX 100 MG/5 ML SUSP
61199	ZITHROMAX 200 MG/5 ML SUSP
48793	ZITHROMAX 250 MG TABLET
61198	ZITHROMAX 500 MG TABLET
48795	ZITHROMAX I.V. 500 MG VIAL

Table 4 (concurrent therapy with recommended drugs) **Required quantity: *2*** **Look back timeframe: *NA***

For the list of recommended drug GCNs that pertain to this step, see the Recommended Drug GCN table in the previous “Supporting Tables” section.

Note: Click the hyperlink to navigate directly to the table.

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Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier / Gold Standard, Inc. 2025. Available at www.clinicalpharmacology.com. Accessed on February 26, 2025.

2. Drug Facts and Comparisons. eFacts [online]. 2023. Available from Wolters Kluwer Health, Inc. Accessed on July 31, 2023.

3. Arikayce Prescribing Information. Bridgewater, NJ. Insmed Incorporated. January 2025.

4. Griffith DE. (2023) Overview of nontuberculous mycobacterial infections of the lungs. Von Reyn CF (Ed.), UpToDate. Accessed on October 6, 2024. Available at www.uptodate.com.

5. Daley CL, Iaccarino JM, Lange C, et al. Treatment of Nontuberculous Mycobacterial Pulmonary Disease: An Official ATS/ERS/ESCMID/IDSA Clinical Practice Guideline. Clin Inf Dis 2020; 71(4):e1-e36.

6. Oliver KN. Inhaled amikacin for treatment of refractory pulmonary nontuberculous mycobacterial disease. Ann Am Thorac Soc 2014; 11(1).

7. Jhun BW. Amikacin Inhalation as salvage therapy for refractory nontuberculous mycobacterial lung disease. Antimicrob Agents Chemother 2018; 62(7).

8. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on February 26, 2025.

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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
02/17/2021	• Annual review by staff • Removed GCNs for Avelox (discontinued) and ofloxacin (not on formulary) from Table 3 • Added GCNs for ciprofloxacin IV (52121 and 52122), levofloxacin IV (89596, 47075 and 47072) and zithromax IV (48795) • Updated references
07/05/2022	• Annual review by staff • Updated references
08/15/2023	• Annual review by staff • Updated references
01/24/2025	• Annual review by staff • Updated references