

**Texas Prior Authorization Program
Clinical Criteria**

Drug/Drug Class**Arikayce (Amikacin liposome inhalation
suspension)**

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**Arikayce (Amikacin)**

- **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

- 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



Arikayce (Amikacin)

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 |
|-----------------------------|-------|
| ARIKAYCE 590 MG/8.4 ML VIAL | 45435 |



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Clinical Criteria Logic

1. Is the client greater than or equal to (\geq) 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

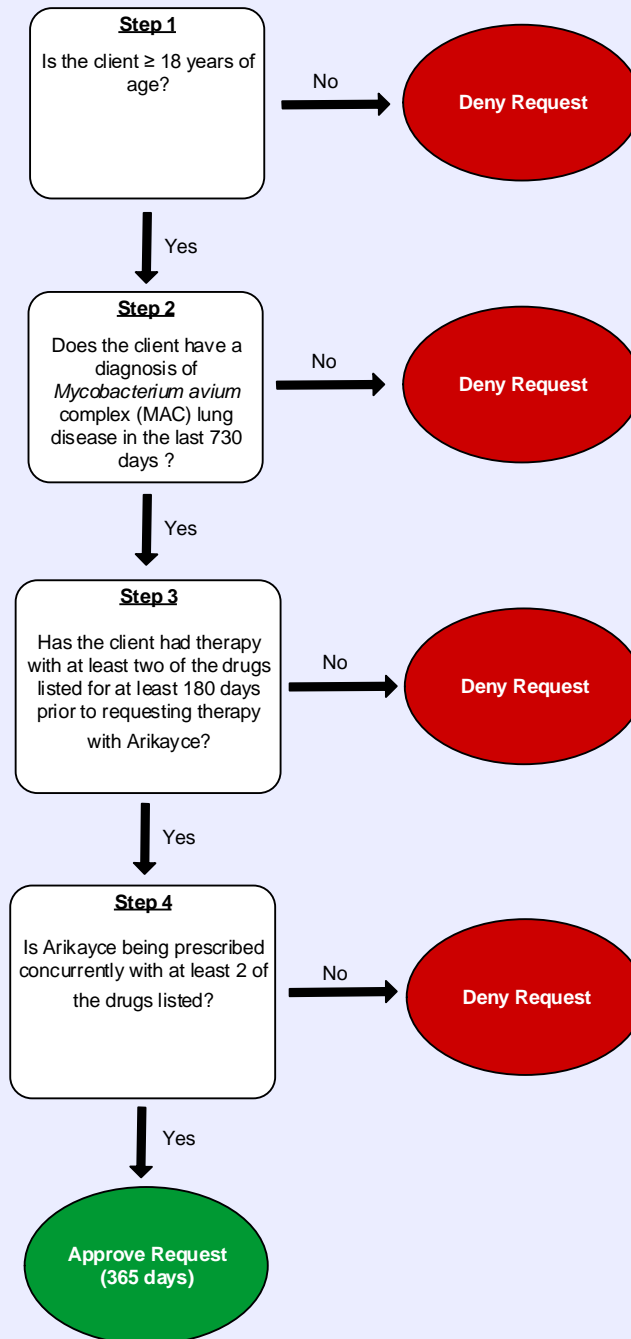
3. Has the client had therapy with at least two of the **drugs listed** for at least 180 days in the last 365 days prior to requesting therapy with Arikayce?
 Yes – Go to #4
 No – Deny

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

| Step 2 (diagnosis of <i>Mycobacterium avium</i> 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) |

| Step 3 (claims for drugs recommended as prior multi-drug therapy) Required quantity: 2 (180 days total therapy) Look back timeframe: 365 days | |
|--|---------------------------------------|
| GCN | Label Name |
| 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 |
| 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 |

| Step 3 (claims for drugs recommended as prior multi-drug therapy) | |
|--|---------------------------------|
| Required quantity: 2 (180 days total therapy) | |
| Look back timeframe: 365 days | |
| 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 |
| 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 |

Step 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. 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. Arikayce Prescribing Information. Bridgewater, NJ. Inmed Incorporated. March 2020.
4. Griffith DE. (2019) Overview of nontuberculous mycobacterial infections in HIV-negative patients. Von Reyn CF (Ed.), UpToDate. Accessed on April 26, 2019. Available at www.uptodate.com.
5. Currier JS. (2019) Mycobacterium avium complex (MAC) infections in HIV-infected patients. Bartlett JG (Ed.), UpToDate. Accessed on April 26, 2019. Available at www.uptodate.com.
6. Daley CL. Mycobacterium avium Complex Disease. Microbiol Spectr 2017 Apr;5(2).
7. Oliver KN. Inhaled amikacin for treatment of refractory pulmonary nontuberculous mycobacterial disease. Ann Am Thorac Soc 2014; 11(1).
8. Jhun BW. Amikacin Inhalation as salvage therapy for refractory nontuberculous mycobacterial lung disease. Antimicrob Agents Chemother 2018; 62(7).



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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 | 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 |