

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1264-4
Program	Prior Authorization/Notification
Medication	Arikayce® (amikacin liposome inhalation suspension)
P&T Approval Date	11/2018, 11/2019, 11/2020, 11/2021
Effective Date	2/1/2022; Oxford only: N/A

1. Background:

Arikayce is an aminoglycoside antibacterial indicated in adults who have limited or no alternative treatment options, for the treatment of *Mycobacterium avium* complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. As only limited clinical safety and effectiveness data for Arikayce are currently available, reserve Arikayce for use in adults who have limited or no alternative treatment options. This drug is indicated for use in a limited and specific population of patients.¹

This indication is approved under accelerated approval based on achieving sputum culture conversion (defined as 3 consecutive negative monthly sputum cultures) by Month 6. Clinical benefit has not yet been established.¹

Limitation of Use:

Arikayce has only been studied in patients with refractory MAC lung disease defined as patients who did not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. The use of Arikayce is not recommended for patients with non-refractory MAC lung disease.¹

2. Coverage Criteria:

A. Initial Authorization

1. Arikayce will be approved based on **all** of the following criteria:

- a. Diagnosis of *Mycobacterium avium* complex (MAC) lung disease

-AND-

- b. Patient has not achieved negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy (e.g. macrolide, rifampin, & ethambutol) within the past 12 months

-AND-

<p>c. Patient has limited or no alternative treatment options</p> <p style="text-align: center;">-AND-</p> <p>d. Used as part of a combination antibacterial drug regimen</p> <p>Authorization will be issued for 6 months.</p> <p>B. <u>Reauthorization</u></p> <p>1. Arikayce will be approved based on the following criterion:</p> <p>a. Patient has achieved negative sputum cultures</p> <p>Authorization will be issued for 12 months.</p>
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3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
- Medical Necessity may be in place.

4. References:

1. Arikayce [package insert]. Bridgewater, NJ: Inmed; October 2020

Program	Prior Authorization/Notification – Arikayce® (amikacin liposome inhalation suspension)
Change Control	
11/2018	New program
11/2019	Annual review. No changes.
11/2020	Annual review. References updated.
11/2021	Annual review. Updated clinical criteria to reflect labeled indication. Updated reference.