UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1264-8
Program	Prior Authorization/Notification
Medication	Arikayce® (amikacin liposome inhalation suspension)
P&T Approval Date	11/2018, 11/2019, 11/2020, 11/2021, 11/2022, 11/2023, 11/2024, 11/2025
Effective Date	2/15/2026

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]:

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-

   c. Patient has limited or no alternative treatment options

   -AND-

d. Used as part of a combination antibacterial drug regimen

Authorization will be issued for 6 months.

B. Reauthorization

1. **Arikayce** will be approved based on the following criterion:

   a. Patient has achieved negative sputum cultures

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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 [packae insert]. Bridgewater, NJ: Insmed; July 2025

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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.
11/2022	Annual review with no change to clinical criteria. Added state mandate footnote.
11/2023	Annual review with no change to clinical criteria. Updated reference.
11/2024	Annual review with no change to clinical criteria.
11/2025	Annual review with no change to clinical criteria. Updated reference.