

Arikayce (liposomal amikacin)

Coverage Criteria:

Reserved for patients who meet the following criteria:

1. Prescribed by or in consultation with an infectious disease specialist; and,
2. Patient is ≥ 18 years of age; and,
3. Patient is diagnosed with refractory mycobacterium avium complex (MAC), defined as:
 - a. Documented positive MAC sputum or bronchoscopy cultures; and,
 - b. Cultures remain positive while being treated for at least 6 months with guideline based multidrug antibiotic therapy (such as combination of a macrolide, rifampin and ethambutol); and,
 - c. Patient has been adherent to prior antibiotic regimens; and
4. Patient is unable to use nebulized IV amikacin due to limitations with self-administering the product; and,
5. Patient does not have one of the following contraindications to Arikayce:
 - a. Cystic fibrosis; or,
 - b. Active pulmonary tuberculosis; or,
 - c. Amikacin resistant MAC isolates (minimum inhibitory concentrations ≥ 64 $\mu\text{g/ml}$); or,
 - d. Active malignancy; and,
6. Prescribed within FDA approved dosing regimen.

Coverage Duration:

Initial authorization will be provided for 6 months

Reauthorization will be provided for 6 months

Other Criteria:

Arikayce 540 mg/8.4 ml vials: 30 vials per 30 days

Renewal Criteria:

1. Patient has been adherent to the antibiotic treatment regimen; and,
2. Documentation patient has achieved negative sputum cultures.