

## Pharmacy Policy Bulletin

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**Title:** Amikacin Liposome Inhalation Suspension (Arikayce®)

**Policy #:** Rx.01.213

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**Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.**

**This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.**

**Members are advised to use participating pharmacies in order to receive the highest level of benefits.**

**Intent:**

The intent of this policy is to communicate the medical necessity criteria for **amikacin liposome inhalation suspension (Arikayce®)** as provided under the member's prescription drug benefit.

**Description:**

*Mycobacterium avium complex* (MAC) is the most common pulmonary nontuberculous mycobacterial (NTM) infections of the lung in almost all regions of the world. Antimycobacterial treatment is prolonged and potentially difficult to tolerate and should only be considered in individuals who meet the clinical, radiographic, and microbiologic criteria for the diagnosis of nontuberculous mycobacterial infection. Three-drug combination regimen is recommended for those treated for MAC pulmonary disease and treatment is continued until sputum cultures are consecutively negative for at least 12 months.

Amikacin liposome inhalation suspension (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.

**Policy:**

**INITIAL CRITERIA:** Arikayce® (amikacin liposome inhalation suspension) is approved when ALL of the following are met:

1. Diagnosis of refractory *Mycobacterium avium complex* (MAC) lung disease; and
2. Member has not achieved negative sputum cultures after a minimum of 6 consecutive months of multidrug background regimen therapy; and
3. Documentation that the medication will be used as part of a combination antibacterial regimen; and
4. Member is 18 years of age or older; and
5. Prescribed by or in consultation with a pulmonologist or infectious diseases specialist

Initial authorization: 6 months

**REAUTHORIZATION CRITERIA:** Arikayce® (amikacin liposome inhalation suspension) is re-approved when both of the following criteria are met:

1. Documentation of positive clinical response to therapy; and
2. Documentation that the medication will be used as part of a combination antibacterial regimen

Reauthorization: 12 months

**Black Box Warning as shown in the drug Prescribing Information:**

**WARNING: RISK OF INCREASED RESPIRATORY ADVERSE REACTIONS**

ARIKAYCE has been associated with a risk of increased respiratory adverse reactions, including, hypersensitivity pneumonitis, hemoptysis, bronchospasm, and exacerbation of underlying pulmonary disease that have led to hospitalizations in some cases.

**Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**

Arikayce® (amikacin liposome inhalation suspension) [prescribing information]. Bridgewater, NJ. Insmmed®. September 2018. Available at: <https://www.arikayce.com/pdf/full-prescribing-information.pdf>. Accessed July 16, 2021.

Kasperbauer, S. Treatment of Mycobacterium avium complex lung infections in adults. UpToDate Web site. August 2018. [www.uptodate.com](http://www.uptodate.com). Accessed July 16, 2021.

**Applicable Drugs:**

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

**Brand Name**

Arikayce®

**Generic Name**

Amikacin liposome inhalation suspension

**Cross References:**

Rx.01.33 Off-Label Use

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<b>Policy Version Number:</b>	3.00
<b>P&amp;T Approval Date:</b>	June 10, 2021
<b>Policy Effective Date:</b>	October 01, 2021
<b>Next Required Review Date:</b>	June 10, 2022

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The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.