

# Amikacin liposomal Inhalation Solution (ALIS)

## Criteria for Use

June 2019

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

**The Product Information should be consulted for detailed prescribing information.**

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTERnet](#) or [PBM INTRAnet](#) site for further information. Note that ARIKAYCE was approved under the FDA Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD), aimed at a limited population (refractory MAC)

## Exclusion Criteria

- Indication other than refractory *Mycobacterium avium* (MAC) pulmonary disease

## Inclusion Criteria

**The answers to ALL of the following must be fulfilled in order to meet criteria**

- Prescriber is an Infectious Diseases or Pulmonary Specialist
- Patient has been treated with at least 6 months of guideline-based therapy without converting sputum cultures to negative (≥6-month final cultures remain positive)
- Patient has failed or is intolerant of parenteral aminoglycoside therapy or is not a candidate for such therapy

## Discontinuation criteria

- If the patient does not convert sputum cultures to negative with 6 months of ALIS + guideline-based therapy for refractory disease (≥6 month final culture results), therapy should be discontinued

For more information, please see the prescribing information or [amikacin liposomal inhalation solution \(ARIKAYCE\) drug monograph](#)

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