



ARIKAYCE
(amikacin liposome inhalation suspension)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Arikayce (amikacin liposome inhalation suspension) is an antibacterial drug. It is an aminoglycoside antibiotic that is inhaled into the lungs once daily through a specialized device, the Lamira Nebulizer System. It is indicated for use in combination with other antibacterial drugs to treat adult patients with a rare lung disease caused by *Mycobacterium avium* complex (MAC) despite six months or longer of standard multidrug treatment (1).

Regulatory Status

FDA-approved indication: 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 (1).

Trial 1 (NCT#02344004) was an open-label, randomized (2:1), multi-center Phase 3 trial in patients with refractory MAC lung disease as confirmed by at least 2 sputum culture results (1). This study excluded MAC lung disease resistant to amikacin, as identified by a minimum inhibitory concentration (MIC) susceptibility greater than 64 mcg/mL. Subjects with a MIC of 64 mcg/mL were allowed to participate in the study (2).

Arikayce has a boxed warning for risk of increased respiratory adverse reactions. Arikayce may cause respiratory adverse reactions including hypersensitivity pneumonitis, hemoptysis, bronchospasm, and exacerbation of underlying pulmonary disease. Patients should be monitored and if any of these reactions occurs, patients should be treated as medically appropriate (1).

Other warnings for Arikayce include ototoxicity, nephrotoxicity, neuromuscular blockade, and embryo-fetal toxicity. Patients should be closely monitored if they have known or suspected auditory or vestibular dysfunction, suspected renal dysfunction, or suspected neuromuscular disorders such as myasthenia gravis (1).

The safety and effectiveness of Arikayce in pediatric patients have not been established (1).



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Summary

Arikayce (amikacin liposome inhalation suspension) is an antibacterial drug. It is an aminoglycoside antibiotic that is inhaled into the lungs once daily through a specialized device, the Lamira Nebulizer System. It is indicated for use in combination with other antibacterial drugs to treat adult patients with a rare lung disease caused by *Mycobacterium avium* complex (MAC) despite six months or longer of standard multidrug treatment. The safety and effectiveness of Arikayce in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Arikayce while maintaining optimal therapeutic outcomes.

References

1. Arikayce [package insert]. Bridgewater, NJ: Insmed Incorporated; February 2023.
2. ClinicalTrials.gov [online]. NIH U.S. National Library of Medicine. 2000. Liposomal Amikacin for Inhalation (LAI) INS-212; 2016 Feb 22. Available at:
https://clinicaltrials.gov/ProvidedDocs/04/NCT02344004/Prot_002.pdf