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5.01.048

Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Anti-Infective Agents	**Original Policy Date:**	October 19, 2018
Subject:	Arikayce	**Page:**	1 of 5

Last Review Date: March 6, 2026

Arikayce

Description

Arikayce (amikacin liposome inhalation suspension)

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).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Arikayce may be considered **medically necessary** if the conditions indicated below are met.

Arikayce may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Mycobacterium avium complex (MAC) lung disease

AND ALL of the following:

1. Diagnosis has been confirmed by at least 2 sputum cultures
2. Inadequate treatment response to at least 6 consecutive months of a multidrug regimen
3. Alternative treatment options have been ruled out
4. Culture shows that the MAC isolate is susceptible to amikacin with a minimum inhibitory concentration (MIC) of ≤ 64 mcg/mL
5. Arikayce will be given with other antibacterial drugs

6. Patients with a history of hyperactive airway disease will pre-treat with an inhaled bronchodilator
7. Prescriber agrees to monitor for respiratory adverse reactions
8. Pregnant patients and female patients of reproductive potential will be advised of the potential adverse effects to the fetus

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Mycobacterium avium complex (MAC) lung disease

AND ALL of the following:

1. Patient has demonstrated clinical benefit while on Arikayce
2. Patient has not achieved 12 consecutive months of negative sputum cultures
3. Arikayce will be given with other antibacterial drugs
4. Patients with a history of hyperactive airway disease will pre-treat with an inhaled bronchodilator
5. Prescriber agrees to monitor for respiratory adverse reactions
6. Pregnant patients and female patients of reproductive potential will be advised of the potential adverse effects to the fetus

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 84 vials* per 84 days

Duration 12 months

*Vials supplied with Lamira Nebulizer System

Prior – Approval *Renewal* Limits

Quantity 84 vials per 84 days

Duration 12 months

Rationale

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; December 2025.
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

Policy History

Date	Action
October 2018	Addition to PA
November 2018	Annual review
March 2019	Annual review. Changed renewal requirement to “patient has not achieved consecutive monthly negative sputum cultures in 6 months” and added requirement that culture shows MAC sensitivity to aminoglycosides per SME
March 2020	Changed renewal quantity to 196 vials for 196 days per FEP
June 2020	Annual review and reference update
September 2020	Changed requirement from “culture shows MAC sensitivity to aminoglycosides” to “culture shows that the MAC isolate is susceptible to amikacin with a minimum inhibitory concentration (MIC) of < 64 mcg/mL”

	per FEP
December 2020	Annual review and reference update
March 2021	Annual review. Changed the MIC requirement from <64 mcg/mL to ≤64mcg/mL per FEP
March 2022	Annual review and reference update
March 2023	Annual editorial review and reference update. Changed “patients of childbearing potential” in requirements to “female patients of reproductive potential” for consistency. Changed policy number to 5.01.048
June 2023	Annual review and reference update
March 2024	Annual review
June 2024	Annual review
March 2025	Annual review
June 2025	Annual review
October 2025	Per reconsideration review, altered requirement of 6 monthly negative sputum cultures to 12 months, added requirement of clinical benefit in continuation, changed duration of both initiation and continuation to 12 months without renewal limit
December 2025	Annual review and reference update
March 2026	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.