

Policy Name:	Arikayce (amikacin liposomal)	Policy #:	2685P
---------------------	--------------------------------------	------------------	--------------

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Arikayce.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Arikayce under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

- 1.1 Documented diagnosis of Mycobacterium avium complex (MAC) lung disease
- 1.2 Sputum, or lung secretion, sample is positive for the infection
- 1.3 Sputum samples are still positive after at least 6 months in a row of using multiple drugs for MAC lung disease
 - Examples are: clarithromycin (or azithromycin), rifampin, and ethambutol
- 1.4 Documentation that Arikayce will be used as part of a multi-drug regimen with the Lamira Nebulizer system
- 1.5 Prescribed by or in consultation with a pulmonologist (lung doctor) or infectious disease specialist

2. Quantity Limit

- 2.1 A Managed Dose Limit will be in place to limit to 30 vials every 30 days

3. Exclusion Criteria

- 3.1 Arikayce will not be covered for patients with non-refractory MAC lung disease
 - Amikacin oral inhalation has only been studied in patients with refractory MAC lung disease defined as patients who did not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. The use of amikacin is not recommended for patients with non-refractory MAC lung disease.
- 3.2 Contraindicated in patients with a known hypersensitivity to any aminoglycoside

4. Approval Period

- 4.1 Initial Approval: 12 months
- 4.2 Reapproval: 12 months with documentation of negative sputum sample
 - American Thoracic Society and Infectious Diseases Society of America (ATS/IDSA) guidelines state that patients should continue to be treated until they have negative samples for 1 year
 - Patients that have had negative cultures for 1 year will not be approved for continued treatment

CPT Codes

--	--

HCPCS Codes

--	--

References

1. Arikayce (amikacin liposome inhalation suspension) [prescribing information]. Bridgewater, NJ: Inmed; February 2023.
2. Daley CL, Iaccarino JM, Lange C, et al. Treatment of Nontuberculous Mycobacterial Pulmonary Disease: An Official ATS/ERS/ESCMID/IDSA Clinical Practice Guideline. Clin Infect Dis. 2020 Aug 14;71(4):905-913.

Created Date: 06/05/19

Effective Date: 06/05/19

Posted to Website: 01/01/22

Revision Date: 02/05/25

DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.