

Clinical Policy Title:	amikacin
Policy Number:	RxA.017
Drug(s) Applied:	Arikayce®
Original Policy Date:	02/07/2020
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Mycobacterium Avium Complex (MAC) (must meet all):

1. Diagnosis of MAC;
2. Prescribed as part of a combination antibacterial drug regimen;
3. Failure, as evidenced by positive sputum culture, of at least a 6-month trial of a combination antibacterial drug regimen, unless contraindicated or clinically significant adverse effects are experienced;
4. Prescribed by or in consultation with an infectious disease specialist or a pulmonologist.

Approval duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Mycobacterium Avium Complex (MAC) (must meet all):

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met the initial approval criteria.
2. Patient has not achieved negative sputum culture conversion by month 6;
3. Arikayce will be given with other antibacterial drugs.

Approval duration

All Lines of Business (except Medicare): 12 months

References

1. Olivier KN, Griffith DE, Eagle G, et al. Randomized trial of liposomal amikacin for inhalation in nontuberculous mycobacterial lung disease. *Am J Respir Crit Care Med*. 2017;195(6):814-823. Available at: <https://www.atsjournals.org/doi/10.1164/rccm.201604-0700OC> . Accessed March 20, 2025.
2. Griffith DE, Eagle G, Thomson R, et al. Amikacin liposome inhalation suspension for treatment-refractory lung disease caused by mycobacterium avium complex (Convert). A prospective, open-label, randomized study. *Am J Respir Crit Care Med*. 2018;198(12):1559-1569. Available at: <https://www.atsjournals.org/doi/citedby/10.1164/rccm.201807-1318OC>. Accessed March 20, 2025.
3. Griffith DE, Aksamit T, Brown-Elliott BA, et al. An official ats/idsa statement: diagnosis, treatment, and prevention of nontuberculous mycobacterial diseases. *Am J Respir Crit Care Med*. 2007;175(4):367-416. Available at: <https://www.atsjournals.org/doi/full/10.1164/rccm.200604-571ST> . Accessed March 20, 2025.
4. Daley CL, Iaccarino JM, Lange C, et al. Treatment of nontuberculous mycobacterial pulmonary disease: an official ATS/ERS/ESCMID/IDSA clinical practice guideline. *European Respiratory Journal*. 2020;56(1). Available at:

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<https://erj.ersjournals.com/content/56/1/2000535>. Accessed March 20, 2025.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
References updated. No policy changes.	05/2020	05/20/2020
Policy was reviewed: <ol style="list-style-type: none"> Clinical policy title table was updated. Initial therapy criteria I.A.5 and continued therapy criteria II.A.3 were updated to include vial size for maximum dosing. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." References were updated. 	02/01/2021	03/09/2021
Policy was reviewed: <ol style="list-style-type: none"> Initial Approval Criteria, I.A.4: Updated to include requirement for combination therapy with antibiotic. Continued Therapy Criteria II.A.: Updated to add Member has not received more than 12 months of treatment following conversion to negative sputum status; References were reviewed and updated. 	11/22/2021	01/17/2022
Policy was reviewed: <ol style="list-style-type: none"> References were reviewed and updated. 	07/05/2022	10/19/2022
Policy was reviewed: <ol style="list-style-type: none"> Removed prior age criteria. Removed prior dosing criteria. Added requirement to try/fail combination antibacterial drug regimen. Updated approval duration. Added reauthorization requirement for use of other antibacterial drugs in combination with Arikayce. Removed reauthorization requirement of not more than 12 	12/18/2023	1/1/2024

months of treatment since converting to negative sputum status. 7. References were reviewed and updated.		
Policy was reviewed: 1. Removed prescriber criteria. 2. Updated continuation of therapy language.	03/20/2025	04/10/2025
Policy reviewed.	12/11/2025	12/11/2025