

Market Applicability					
Market	GA	KY	MD	NJ	NY
Applicable	X	NA	X	X	X

Arikayce (amikacin liposome inhalation suspension)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Arikayce (amikacin liposome inhalation suspension) 590 mg/8.4 ml vial	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Arikayce (amikacin) may be approved if the following criteria are met:

- I. Individual has a diagnosis of *Mycobacterium avium complex* (MAC) lung disease; **AND**
- II. Individual has received at least six consecutive months of treatment with a multidrug antibacterial regimen and has not achieved negative sputum cultures; **AND**
- III. Individual is using in combination with other antibacterial agents.

Continuation requests for Arikayce (amikacin) may be approved if the following criteria are met:

- I. Individual is using in combination with other antibacterial agents for the treatment of *Mycobacterium avium complex* (MAC) lung disease; **AND**
- II. Individual has achieved negative sputum culture conversion.

Arikayce (amikacin) may **not** be approved for the following:

- I. Individual is using in combination with an intravenous aminoglycoside (such as amikacin or streptomycin) (Griffith 2018); **OR**
- II. Individual has MAC isolates with amikacin resistance (minimum inhibitory concentration [MIC] ≥ 128 $\mu\text{g/mL}$) (ATS/ERS/ESCMID/IDSA 2020).

Note:

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New Program Date 04/15/2019

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Arikayce has a black box warning for risk of increased respiratory adverse reactions. Arikayce has been associated with respiratory adverse reactions including hypersensitivity pneumonitis, hemoptysis, bronchospasm and exacerbation of underlying pulmonary disease that has led to hospitalization.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: December 13, 2020.
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;71(4):905-913.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. 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 Car Med*. 2018 Sep 14. doi: 10.1164/rccm.201807-1318OC.
5. Kasperbauer S, Daley CL. Treatment of Mycobacterium avium complex pulmonary infection in adults. Last updated: November 12, 2020. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: December 13, 2020.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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