Pharmacy Policy Bulletin: J-0847 Arikayce (amikacin) – Commercial and Healthcare Reform	
Number: J-0847	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0847-008	**Original Date:** 01/30/2019
Effective Date: 12/20/2024	**Review Date:** 12/04/2024

Drugs Product(s):	• Arikayce (amikacin) liposome inhalation suspension
FDA-Approved Indication(s):	• 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. As only limited clinical safety and effectiveness data for Arikayce are currently available, reserve Arikayce for use in adults who have limited or no alternative treatment options. This drug is indicated for use in a limited and specific population of patients.

Background:	• As a bactericidal aminoglycoside, Arikayce binds to the 30S ribosomal subunit of bacteria, disrupting and inhibiting protein synthesis.
	• Arikayce should only be administered by nebulization using the Lamira Nebulizer System.
	• While *Mycobacterium avium (M. avium*) is commonly found in resources like food and water, infection is more likely to occur in those with impaired immune systems, such as HIV-infected individuals with CD4 counts less than 50 cells/mm^3.
	• Cornerstones of MAC therapy includes a macrolide (i.e. clarithromycin or azithromycin) and ethambutol. These agents can be used in combination with a "companion" drug, often a rifamycin but potentially an injectable aminoglycoside. Duration of therapy is long-term with some studies suggesting patients continue therapy for at least 12 months after culture conversion.
	• Arikayce is not recommended for initial therapy, but is strongly recommended to be added to the treatment regimen in patients with MAC pulmonary disease who have failed therapy after at least 6 months of guideline-based therapy.
	• Prescribing Considerations:
	  ○ Arikayce should not be used in pregnant patients.
	  ○ Arikayce should be prescribed by an infectious disease specialist.
	  ○ Arikayce has a black box warning for an increased risk of respiratory adverse reactions including hypersensitivity pneumonitis, hemoptysis,

	bronchospasm, and exacerbation of underlying pulmonary disease that have led to hospitalizations in some cases.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Arikayce may be approved when all of the following criteria are met **(A., B., and C.)**:

- **A.** The member has a diagnosis of *Mycobacterium avium complex* (MAC) lung disease. (ICD-10: A31.0)
- **B.** The prescriber attests that the member did not achieve negative sputum cultures despite at least six (6) consecutive months of treatment with a multidrug background regimen that has utilized at least two (2) of the following agents **(1., 2., or 3.)**:
  - **1.** A macrolide (e.g., clarithromycin or azithromycin)
  - **2.** A rifamycin (e.g., rifampin, rifabutin)
  - **3.** Ethambutol
- **C.** Arikayce will continue to be used in conjunction with a background multidrug regimen.

II. Reauthorization

When a benefit, reauthorization of Arikayce may be approved when all of the following criteria are met **(A. and B.)**:

- **A.** The prescriber attests that additional therapy is needed as the member has experienced one (1) of the following **(1. or 2.):**
  - **1.** Positive sputum cultures
  - **2.** Negative sputum cultures for an insufficient period of time (e.g., less than 12 months)
- **B.** Arikayce will continue to be used in conjunction with a background multidrug regimen.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Arikayce [package insert]. Bridgewater, NJ: Insmed; February 2023.
2. 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; 175:367-416.

3. 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):e1-e36.