

## Commercial/Healthcare Exchange PA Criteria

*Effective: March 8<sup>th</sup>, 2019*

**Prior Authorization:** Arikayce

**Products Affected:** Arikayce (amikacin liposome) Inhalation Suspension

**Medication Description:** Arikayce is an oral suspension that is inhaled using the Lamira Nebulizer system. Arikayce is indicated for the treatment of pulmonary Mycobacterium avium complex (MAC) infection, as part of a multidrug regimen in patients with limited or no alternative treatment options.

**Covered Uses:** Treatment of refractory pulmonary MAC in combination with a multidrug regimen in patients with limited or no alternative treatment options.

**Exclusion Criteria:**

1. Pediatric patients less than 18 years of age
2. Patients with a known hypersensitivity to any aminoglycoside

**Required Medical Information:**

1. Diagnosis
2. Previous therapies tried
3. Current therapy regimen

**Age Restrictions:** 18 years of age or older

**Prescriber Restrictions:** Prescribed by an infectious disease specialist or pulmonologist.

**Coverage Duration:** Initial approval: 6 months, Renewal: 12 months (once\*)

**Other Criteria:**

**Initial**

- A. Diagnosis of Mycobacterium avium complex (MAC) lung disease as confirmed by a MAC-positive sputum culture; **AND**
- B. Patient must have a positive sputum culture obtained after at least 6 months of compliant use of a multi-drug regimen for MAC lung disease with a macrolide (clarithromycin or azithromycin), rifampin, and ethambutol; **AND**
- C. Arikayce must be used as part of a multi-drug regimen and will not be approved for use as a single agent.

**Renewal**

- A. Patient has demonstrated response to therapy with the addition of Arikayce, defined as a negative sputum culture obtained within the last 30 days of renewal.

\* Patients that have had negative cultures for 1 year will not be approved for continued treatment. Treatment beyond the first recertification approval (after 18 months) will require documentation of a positive sputum culture to demonstrate the need for continued treatment.

**References:**

1. Arikayce [package insert]. Bridgewater, NJ; Insmed; February 2019.
2. UpToDate. Treatment of Mycobacterium avium complex lung infection in adults. Available at: <https://www.uptodate.com/>. Assessed October 22, 2018.
3. Yagi H, Ishii M, Namkoong H, et al. The efficacy, safety, and feasibility of inhaled amikacin for the treatment of difficult-to-treat non-tuberculous mycobacterial lung diseases. BMC Infect Dis. 2017; 17: 558. doi: 10.1186/s12879-017-2665
4. Griffith DE, Aksamit T, Brown-Ellicott BA, et al. An official ATS/IDSA statement: Diagnosis, treatment, and prevention of nontuberculous mycobacterial diseases. 2007. Am J Respir Crit Care Med. 2007;175:367-416. doi: 10.1164/rccm.200604-571ST.
5. Johnson MM, Odell JA. Nontuberculous mycobacterial pulmonary infections. J Thorac Dis. 2014; 6(3): 210–220. doi: 10.3978/j.issn.2072-1439.2013.12.24.
6. Quon BS, Goss CH, Ramsey BW. Inhaled Antibiotics for Lower Airway Infections. Ann Am Thorac Soc. 2014;11(3):425–434. DOI: 10.1513/AnnalsATS.201311-395FR.

**Policy Revision history**

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	03/06/2019