Reference number(s)
3150-A

Specialty Guideline Management
Arikayce

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Arikayce	amikacin liposome inhalation suspension

Indications[1]

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Arikayce is indicated in 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.

Limitation of Use

Arikayce 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 Arikayce is not recommended for patients with non-refractory MAC lung disease.

All other indications are considered experimental/investigational and are not medically necessary.

Coverage Criteria

Mycobacterium avium complex (MAC) lung disease[1,3]

Authorization of 12 months may be granted for members with mycobacterium avium complex (MAC) lung disease when all of the following criteria are met:

- The patient has refractory disease with limited or no other treatment options.
- The requested medication will be used as part of a combination antibacterial drug regimen.
- The patient has not achieved negative sputum cultures after being treated with a multidrug background regimen therapy for a minimum of 6 consecutive months.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section who are experiencing benefit from therapy as evidenced by disease stability or disease improvement (e.g., achievement and maintenance of negative sputum cultures).

References

1. Arikayce [package insert]. Bridgewater, NJ: Insmed Incorporated; February 2023.
2. Griffith, DE, Aksamit, T, Brown-Elliott, BA, et al. An Official ATS/IDSA Statement: Diagnosis, Treatment, and Prevention of Nontuberculous Mycobacterial Disease Am J Respir Crit Care Med. 2007;175(4):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 [published correction appears in Clin Infect Dis. 2020 Dec 31;71(11):3023]. Clin Infect Dis. 2020;71(4):e1-e36.