

Effective date:4/15/19
Reviewed:4/2/20, 2/2021, 1/2022, 1/2023, 2/2024, 01/2025
Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

ARIKAYCE (amikacin liposome inhalation suspension)

POLICY

I. INDICATIONS

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.

II. CRITERIA FOR INITIAL APPROVAL

Mycobacterium avium complex (MAC) lung disease

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

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

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

1. Arikayce [package insert]. Bridgewater, NJ: Inmed Incorporated; January 2025
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):367-416
3. Daley, CL, Iaccarino, JM, Lange, C, et al. Treatment of Nontuberculous Mycobacterial Pulmonary Disease: