UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Arikayce

Program	Prior Authorization
Medication	Arikayce® (amikacin liposome inhalation suspension)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York CHIP, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	11/2018
Pharmacy and Therapeutics Approval Date	2/2021
Effective Date	4/2021

1. Background:

Arikayce is an aminoglycoside antibacterial 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. 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.[1]

This indication is approved under accelerated approval based on achieving sputum culture conversion (defined as 3 consecutive negative monthly sputum cultures) by Month 6. Clinical benefit has not yet been established.[1]

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.[1]

2. Coverage Criteria:

A. Initial Authorization

1. Arikayce will be approved based on **all** of the following criteria:

a. Diagnosis of refractory *Mycobacterium avium* complex (MAC) lung disease

-AND-

b. Submission of medical records (e.g., chart notes, laboratory values) documenting respiratory cultures positive for MAC within the previous 6 months

-AND-

c. Submission of medical records (e.g., chart notes, laboratory values) documenting the following [prescription claims history may be used in conjunction as documentation of medication use, dose, and duration]:

(1) Patient has been receiving a multidrug background regimen containing **at least two** of the following agents for a minimum of 6 consecutive months within the past 12 months:

(a) Macrolide antibiotic [e.g., azithromycin, clarithromycin]
(b) Ethambutol
(c) Rifamycin antibiotic [e.g., rifampin, rifabutin]

-AND-

d. Patient will continue to receive a multidrug background regimen

-AND-

e. Documentation that the patient has not achieved negative sputum cultures after receipt of a multidrug background regimen for a minimum of 6 consecutive months

-AND-

f. *In vitro* susceptibility testing of recent (within 6 months) positive culture documents that the MAC isolate is susceptible to amikacin with a minimum inhibitory concentration (MIC) of $\leq$ 64 mcg/mL

-AND-

g. Prescribed by or in consultation with one of the following:

(1) Infectious disease specialist
(2) Pulmonologist

Authorization will be issued for 6 months.

B. Reauthorization

1. Arikayce will be approved based on **all** of the following criteria:

a. **One** of the following:

(1) Documentation that the patient has achieved negative respiratory cultures

-OR-

(2) **All** of the following:

(a) Patient has not achieved negative respiratory cultures while on Arikayce

-AND-

(b) Physician attestation that patient has demonstrated clinical benefit while on Arikayce

-AND-

(c) In vitro susceptibility testing of most recent (within 6 months) positive culture with available susceptibility testing documents that the MAC isolate is susceptible to amikacin with an minimum inhibitory concentration (MIC) of < 64 mcg/mL

-AND-

(d) Patient has **not** received greater than 12 months of Arikayce therapy with continued positive respiratory cultures

-AND-

b. Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient continues to receive a multidrug background regimen containing **at least two** of the following agents [prescription claims history may be used in conjunction as documentation of medication use, dose, and duration]:

(1) Macrolide antibiotic [e.g., azithromycin, clarithromycin]
(2) Ethambutol
(3) Rifamycin antibiotic [e.g., rifampin, rifabutin]

-AND-

c. Prescribed by or in consultation with one of the following:

(1) Infectious disease specialist
(2) Pulmonologist

Authorization will be issued for 6 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Arikayce [package insert]. Bridgewater, NJ: Insmed; October 2020.
2. Griffith DE, Aksamit T, Brown-Elliot 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. Haworth CS, Banks J, Capstick T, et al. British thoracic society guidelines for the management of non-tuberculous mycobacterial pulmonary disease. Thorax. 2017;72:ii1-ii64.
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 Care Med. 2018; Sep 14. doi: 10.1164/rccm.201807-1318OC. [Epub ahead of print]
5. Kasperbauer S, Daley CL. Treatment of Mycobacterium avium complex lung infection in adults. Bloom A (Ed). UpToDate . Waltham MA: UpToDate Inc. http://www.uptodate.com. Accessed January 30, 2019.
6. Winthrop KL, Morimoto K, Castellotti PK, et al. An open-label extension study of amikacin liposome inhalation suspension (ALIS) for treatment-refractory lung disease caused by mycobacterium avium complex (MAC). Slides presented at: American College of Chest Physicians Annual Meeting; October 19-23, 2019; New Orleans, Louisiana.
7. Daley CL, Iaccarino Jr JM, Lange C, et al. Treatment of Nontuberculous Mycobacterial Pulmonary Disease: An Official ATS/ERS/ESCMID/IDSA Clinical Practice Guideline. Clinical Infectious Diseases. 2020; 71(11):3023.

Program	Prior Authorization –Arikayce
Change Control	

Date	Change
11/2018	New program
3/2019	Added documentation requirements, susceptibility testing, and prescriber check.
2/2020	Updated reauthorization criteria providing coverage for patients with clinical benefit yet have not achieved negative respiratory cultures after 6 months of therapy with Arikayce. Updated references.
11/2020	Annual review. Updated reference.
2/2021	Updated references