



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMIKACIN LIPOSOMAL INHALATION

Generic	Brand	HICL	GCN	Exception/Other
AMIKACIN LIPOSOMAL/NEB. ACCESSR	ARIKAYCE	45298		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Does the patient have a diagnosis of *Mycobacterium avium complex* (MAC) lung disease with limited or no alternative treatment options and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient has **NOT** achieved negative sputum cultures after a minimum of 6 consecutive months of multidrug background regimen therapy
 - Arikayce will be used as part of a combination antibacterial drug regimen
 - Arikayce is being prescribed by or in consultation with a pulmonologist or infectious disease specialist physician

If yes, **approve for 6 months by HICL with a quantity limit of #1 vial (590mg/8.4mL) per day.**

APPROVAL TEXT: Renewal requires the patient has not had a positive MAC sputum culture after consecutive negative cultures and physician attestation of improvement in symptoms. Additionally, for first renewal requests, approval requires documentation of at least one negative sputum culture for MAC by six months of Arikayce treatment. For second and subsequent renewal requests, approval requires documentation of at least three negative sputum cultures for MAC by 12 months of Arikayce treatment.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires a diagnosis of *Mycobacterium avium complex* (MAC) lung disease with limited or no alternative treatment options. In addition, the following criteria must also be met:

- The patient is 18 years of age or older
- The patient has NOT achieved negative sputum cultures after a minimum of 6 consecutive months of multidrug background regimen therapy
- Arikayce will be used as part of a combination antibacterial drug regimen
- Arikayce is being prescribed by or in consultation with a pulmonologist or infectious disease specialist physician

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GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the request for the first renewal of Arikayce for the treatment of patients with a diagnosis of *Mycobacterium avium complex* (MAC) lung disease and the patient meets **ALL** of the following criteria?

- There is documentation of at least **ONE** negative sputum culture for MAC by 6 months of Arikayce treatment
- The patient has **NOT** had a positive MAC sputum culture after consecutive negative cultures
- Physician attestation of improvement in symptoms

If yes, **approve for 6 months by HICL with a quantity limit of #1 vial (590mg/8.4mL) per day.**

If no, continue to #2.

2. Is the request for the second or subsequent renewal of Arikayce for treatment of patients with a diagnosis of *Mycobacterium avium complex* (MAC) lung disease and the patient meets **ALL** of the following criteria?

- There is documentation of at least **THREE** negative sputum cultures for MAC by 12 months of Arikayce treatment
- The patient has **NOT** had a positive MAC sputum culture after consecutive negative cultures
- Physician attestation of improvement in symptoms

If yes, **approve for 6 months by HICL with a quantity limit of #1 vial (590mg/8.4mL) per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires the diagnosis of *Mycobacterium avium complex* (MAC) lung disease for renewal. In addition, the following criteria must be met:

- The patient has not had a positive MAC sputum culture after consecutive negative cultures
- Physician attestation of improvement in symptoms
- The patient meets ONE of the following:
 - For first requests for renewal, approval requires:
 - There is documentation of at least ONE negative sputum culture for MAC by 6 months of Arikayce treatment
 - For second or subsequent requests for renewal, approval requires:
 - There is documentation of at least THREE negative sputum cultures for MAC by 12 months of Arikayce treatment

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Arikayce.

REFERENCES

- Arikayce [Prescribing information]. Bridgewater, NJ: Insmmed Incorporated; September 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 11/18

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P&T Approval: 10/18