



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMIKACIN LIPOSOMAL INHALATION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMIKACIN LIPOSOMAL/NEB. ACCESSR	ARIKAYCE	45298		GPI-10 (0700001012)	

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 given in consultation with a pulmonologist or infectious disease specialist physician

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8.4mL (1 vial) per day.**

APPROVAL TEXT: Renewal requires that the patient has not had a positive MAC sputum culture after consecutive negative cultures and also has had 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: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires the following rule(s) be met for approval:

- A. You have *Mycobacterium avium complex* (MAC – group of bacteria that cause serious infections) lung disease with limited or no alternative treatment options
- B. You are 18 years of age or older
- C. You have NOT achieved negative sputum cultures (mucus tests) after using multidrug background regimen therapy for at least 6 months in a row
- D. Arikayce will be used as part of a combination antibacterial drug regimen
- E. Arikayce is being prescribed by or given in consultation with a pulmonologist (lung doctor) or infectious disease specialist physician

(Initial denial text continued on next page)

CONTINUE ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMIKACIN LIPOSOMAL INHALATION

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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
 - The patient has had an improvement in symptoms

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8.4mL (1 vial) 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
 - The patient has had an improvement in symptoms

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8.4mL (1 vial) per day.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

CONTINUE ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMIKACIN LIPOSOMAL INHALATION

INITIAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires the following rule(s) be met for renewal:

- A. You have *Mycobacterium avium complex* (MAC- group of bacteria that cause serious infections) lung disease
- B. You have not had a positive *Mycobacterium avium complex* sputum culture (mucus test) after repeated negative cultures
- C. You have experienced an improvement in symptoms
- D. You meet ONE of the following:
 - 1. For first renewal requests, approval also requires documentation of at least ONE negative sputum culture (mucus test) for *Mycobacterium avium complex* by 6 months of Arikayce treatment
 - 2. For second or later renewal requests, approval also requires documentation of at least THREE negative sputum cultures (mucus test) for *Mycobacterium avium complex* by 12 months of Arikayce treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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: 05/01/20

Created: 11/18

Client Approval: 04/20

P&T Approval: 10/18