



ARIKAYCE[®]

(amikacin liposome
inhalation suspension)

Limited Population

BE POSITIVE
GET MAC-
NEGATIVE
WITH ARIKAYCE

In a clinical study, adding ARIKAYCE to a multidrug treatment helped 29% (65/224) of people with difficult-to-treat MAC lung disease test MAC-negative at 6 months compared to 8.9% (10/112) of people on a multidrug treatment alone. After 6 months, people on ARIKAYCE did not see an improvement in their 6-minute walk test and St George's Respiratory Questionnaire measurements.

ARIKAYCE is the **first and only FDA-approved treatment** used in combination with multidrug therapy for adults who still test positive for MAC lung disease after at least 6 months on multidrug treatment alone.

ARIKAYCE was approved by FDA using the Limited Population pathway. This means FDA has approved this drug for a limited and specific patient population, and studies on the drug may have only answered focused questions about its safety and effectiveness.

IMPORTANT SAFETY INFORMATION AND BOXED WARNING

ARIKAYCE is associated with a risk of increased respiratory adverse reactions including allergic inflammation of lungs, coughing up blood, severe breathing problems and worsening of COPD.

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including Boxed Warning, at [ARIKAYCE.com](#).

On treatment but still testing positive for MAC?

If you are still testing positive for MAC lung disease, you may be at risk for permanent lung damage—even if you're feeling better.



However, MAC can be hard to treat. If you are still testing positive for MAC, you are not alone. **For 1 in 3 people, multidrug treatment may simply not be enough to test MAC-negative.** That's where ARIKAYCE comes in.



ARIKAYCE is the first and only FDA-approved treatment used in combination with multidrug therapy for adults who still test positive for MAC lung disease after at least 6 months on multidrug treatment alone.

ARIKAYCE was approved by FDA using the Limited Population pathway. This means FDA has approved this drug for a limited and specific patient population, and studies on the drug may have only answered focused questions about its safety and effectiveness.



"To find out my multidrug treatment wasn't working was incredibly disheartening, frustrating, and a little scary. Then I found ARIKAYCE."

—Judy, a real ARIKAYCE patient

Judy was compensated for her time.

IMPORTANT SAFETY INFORMATION AND BOXED WARNING

ARIKAYCE can cause serious side effects, including:

- **allergic inflammation of the lungs.** These respiratory problems may be symptoms of allergic inflammation of the lungs and often come with fever, wheezing, coughing, shortness of breath, and fast breathing
- **coughing up of blood (hemoptysis).** Coughing up blood is a serious and common side effect of ARIKAYCE
- **severe breathing problems.** Severe breathing problems can be symptoms of bronchospasm. Bronchospasm is a serious and common side effect of ARIKAYCE. Bronchospasm symptoms include shortness of breath, difficult or labored breathing, wheezing, and coughing or chest tightness

Experts strongly recommend adding ARIKAYCE

The NTM Treatment Guidelines* created by leading scientific communities strongly recommend adding ARIKAYCE if:



you have **MAC lung disease**



you've been on a **multidrug treatment** for at least 6 months



your sputum tests show you're still testing positive for MAC

Learn more about the NTM Treatment Guidelines at [ARIKAYCE.com/guidelines](https://www.ari kayce.com/guidelines)

*ATS/ERS/ESCMID/IDSA NTM guidelines.

ATS=American Thoracic Society; ERS=European Respiratory Society; ESCMID=European Society of Clinical Microbiology and Infectious Diseases; IDSA=Infectious Diseases Society of America; MAC=*Mycobacterium avium* complex; NTM=nontuberculous mycobacteria.

IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

- **worsening of chronic obstructive pulmonary disease (COPD).** This is a serious and common side effect of ARIKAYCE

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including [Boxed Warning](#), at [ARIKAYCE.com](https://www.ari kayce.com).


ARIKAYCE[®]
(amikacin liposome inhalation suspension)
Limited Population

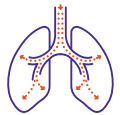
ARIKAYCE targets the MAC infection directly in your lungs



ARIKAYCE is an inhaled antibiotic taken with a nebulizer.



ARIKAYCE is different because the antibiotic is contained inside tiny particles called liposomes, which help it reach the lungs.



When inside the lungs, the liposomes release the antibiotic to fight the MAC infection.

A different way to fight MAC lung disease



"My doctor told me the good news was that there was something for me, an inhaled antibiotic that went directly to my lungs."

-Elisse, a real ARIKAYCE patient

Elisse was compensated for her time.

Watch ARIKAYCE in action at [ARIKAYCE.com/action](https://www.arikeyce.com/action)

IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

ARIKAYCE can cause serious side effects, including: (cont'd)

- **serious allergic reactions.** Serious allergic reactions that may lead to death have happened to people who take ARIKAYCE. Stop taking ARIKAYCE right away and get emergency medical help if you have any of the following symptoms of a serious allergic reaction: hives, itching, redness or blushing of the skin (flushing), swollen lips, tongue or throat, trouble breathing or wheezing, shortness of breath, noisy high-pitched breathing (stridor), cough, nausea, vomiting, diarrhea, feel cramps in your stomach area, fast heart rate, feeling light headed, feeling faint, loss of control of the bowels or bladder (incontinence), and dizziness

While using ARIKAYCE, these side effects may become serious enough that treatment in a hospital is needed. Call your healthcare provider or get medical help right away if you have any of these serious side effects while taking ARIKAYCE. Your healthcare provider may ask you to stop using ARIKAYCE for a short period of time or completely stop using ARIKAYCE.

Do not use ARIKAYCE if you are allergic to any aminoglycoside, or any of the ingredients in ARIKAYCE.

IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

Before using ARIKAYCE, tell your healthcare provider about all medical conditions, including if you:

- have asthma, COPD, shortness of breath, or wheezing (bronchospasm)
- have been told you have poor lung function
- have hearing problems, such as ringing in your ears or hearing loss
- have dizziness or a sense of the room spinning
- have kidney problems

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including [Boxed Warning](#), at [ARIKAYCE.com](https://www.arikeyce.com).


ARIKAYCE[®]
(amikacin liposome inhalation suspension)
Limited Population

Studied in people whose multidrug treatment wasn't working

All of the people in the ARIKAYCE study had been on a multidrug treatment for MAC lung disease for at least 6 months, but were still testing positive for MAC.



224

224 people added ARIKAYCE to their multidrug treatment and 112 people continued to take a multidrug treatment alone



Study objectives:

The study looked at the number of people in each group who tested MAC-negative over time. The study also looked at how long people stayed MAC-negative after completing treatment



Additional objectives:

- Improvement in the distance people walked after 6 minutes*
- Improvement in overall health, daily life, and perceived well-being in people with lung disease (as measured by a questionnaire)*

*6-minute walk test and St George's Respiratory Questionnaire.

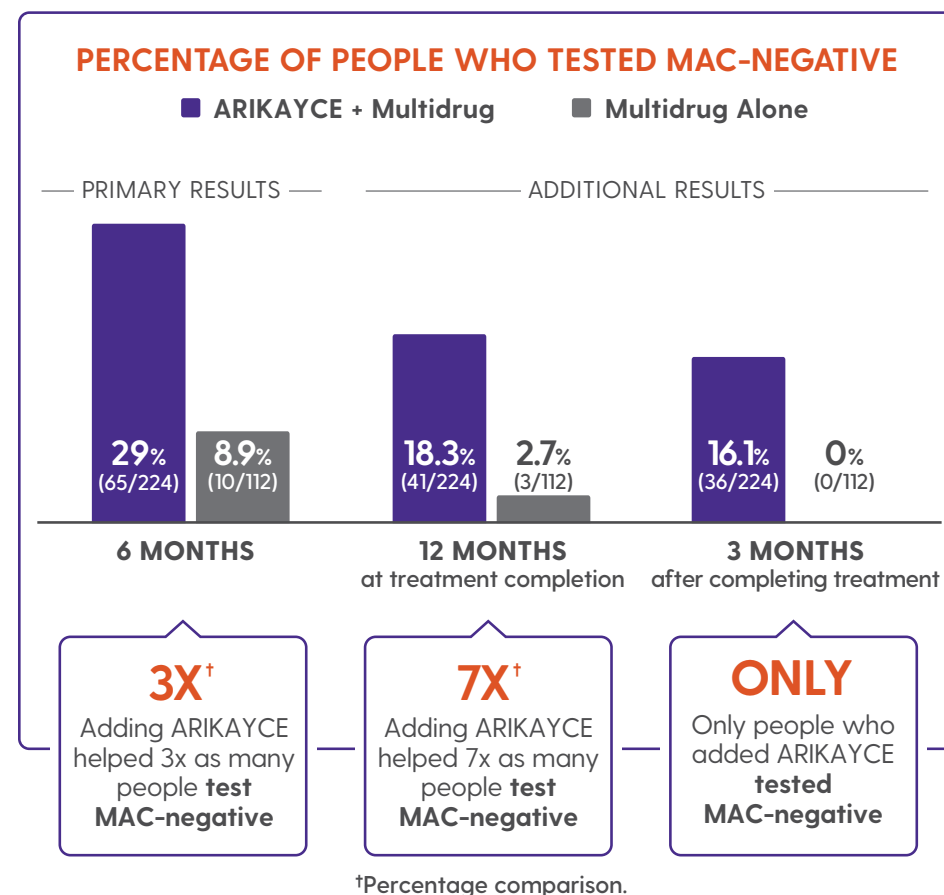
IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

Before using ARIKAYCE, tell your healthcare provider about all medical conditions, including if you: (cont'd)

- have neuromuscular disease, such as myasthenia gravis
- are pregnant or plan to become pregnant. It is not known if ARIKAYCE can harm your unborn baby. ARIKAYCE is in a class of medicines that may be connected with complete deafness in babies at birth. The deafness affects both ears and cannot be changed
- are breastfeeding or plan to breastfeed. It is not known if the medicine in ARIKAYCE passes into your breast milk and if it can harm your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with ARIKAYCE

Proven to help people test MAC-negative and stay MAC-negative even after completing treatment

In a clinical study, adding ARIKAYCE helped more people test MAC-negative for 12 months and beyond.



Additional study results: In the ARIKAYCE clinical study, there was no improvement in the 6-minute walk test and St George's Respiratory Questionnaire measurements at the end of 6 months.

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including [Boxed Warning](#), at [ARIKAYCE.com](#).

ARIKAYCE[®]
(amikacin liposome inhalation suspension)
Limited Population

Understanding possible side effects

Everyone responds to treatment differently. If you have questions about side effects, be sure to speak with your doctor.



ARIKAYCE is associated with a risk of increased respiratory side effects including allergic inflammation of the lungs, coughing up blood, severe breathing problems, and worsening of COPD.



In the clinical study, serious side effects included hearing loss or ringing in the ears (ototoxicity), worsening kidney problems (nephrotoxicity), and worsening muscle weakness (neuromuscular blockade).

19.7% vs 16.1%

19.7% of people in the study who took ARIKAYCE + a multidrug treatment experienced serious side effects

vs

16.1% of people who took a multidrug treatment alone

IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

Tell your healthcare provider about all the medicines you take, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements.

ARIKAYCE may cause serious side effects, including:

- **hearing loss or ringing in the ears (ototoxicity).** Ototoxicity is a serious and common side effect of ARIKAYCE. Tell your healthcare provider right away if you have hearing loss or you hear noises in your ears, such as ringing or hissing. Tell your healthcare provider if you start having problems with balance or dizziness (vertigo)

Common side effects

Experienced by 5% or more of people taking ARIKAYCE plus a multidrug treatment:

Side effect	% of people	Side effect	% of people
• changes to your voice and hoarseness	48%	• headache	10%
• cough	40%	• fever	8%
• muscle pain	18%	• decreased weight	7%
• sore throat	18%	• vomiting	7%
• fatigue	16%	• rash	6%
• diarrhea	13%	• increased sputum	6%
• nausea	12%	• chest discomfort	5%



Cough was first reported most often during the first month of treatment.

What is ARIKAYCE?

ARIKAYCE is used in combination with multidrug therapy for adults who still test positive for MAC lung disease after at least 6 months on multidrug treatment alone.

ARIKAYCE was approved by FDA using the Limited Population pathway. This means FDA has approved this drug for a limited and specific patient population, and studies on the drug may have only answered focused questions about its safety and effectiveness.

ARIKAYCE was studied in adult patients. It is not known if ARIKAYCE is safe and effective in children younger than 18 years of age.





Please see additional Important Safety Information throughout and full [Prescribing Information](#), including [Boxed Warning](#), at [ARIKAYCE.com](#).



Managing side effects on your treatment journey

A telephone survey (conducted during a 2-month period at 2 academic centers) of 26 people on ARIKAYCE looked at how to help manage certain respiratory-related side effects while on treatment. Below are the potential techniques and strategies people used. Always talk to your doctor before starting any management techniques.

Survey disclosures: This information is not included in the ARIKAYCE full Prescribing Information. Writing assistance was provided to the authors through funding from Inmed Incorporated. Inmed was not involved with the conceptualization, development, conduct, or analyses of the study.

Management strategy	 Increased coughing	 Changes in voice and hoarseness (dysphonia)	 Shortness of breath (dyspnea)	 Increased sputum production
Lozenges	•	•		
Soothing fluid intake	•	•		
Warm water or glycerin gargle postdosing	•	•		
Limiting physical activity			•	
Changing ARIKAYCE administration to evening	•	•		
Brief interruptions of ARIKAYCE	•	•	•	
Bronchodilator use (medicine that increases airflow to the lungs)	•		•	
Antitussive agents (cough medicine)	•	•		
Increased supplemental oxygen, if already administering			•	
Airway clearance* (eg, specific breathing techniques, chest percussion, and positive expiratory pressure therapy)				•

*Increased sputum production may be a form of airway clearance in itself.

IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

ARIKAYCE may cause serious side effects, including: (cont'd)

- **worsening kidney problems (nephrotoxicity).** ARIKAYCE is in a class of medicines which may cause worsening kidney problems. Your healthcare provider may do a blood test to check how well your kidneys are working during your treatment with ARIKAYCE

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including **Boxed Warning**, at [ARIKAYCE.com](#).



Map out a treatment plan with your doctor

MAC lung disease is tough and can take time to treat and manage. That's why it's important to keep the lines of communication open with your doctor and establish a treatment plan.

Important things to discuss with your doctor:



Treatment goals A goal of treatment is to test MAC-negative. Ask your doctor how you'll track progress toward this goal



Possible side effects It's important to understand potential side effects and ways to help manage them. Being prepared may help you take your treatment as prescribed



Length of treatment The NTM Treatment Guidelines recommend staying on NTM treatment for at least 12 months after your first MAC-negative test

IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

ARIKAYCE may cause serious side effects, including: (cont'd)

- **worsening muscle weakness (neuromuscular blockade).** ARIKAYCE is in a class of medicines which can cause muscle weakness to get worse in people who already have problems with muscle weakness (myasthenia gravis)

The most common side effects of ARIKAYCE include: changes in voice and hoarseness (dysphonia), cough during or after a dose of ARIKAYCE, especially in the first month after starting treatment, muscle pain, sore throat, tiredness (fatigue), diarrhea, nausea, headache, fever, decreased weight, vomiting, rash, increased sputum, or chest discomfort.

These are not all of the possible side effects of ARIKAYCE. **Call your doctor or pharmacist for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

ARIKAYCE will be delivered to your door

The first shipment from your specialty pharmacy will include:



The ARIKAYCE 28-day Kit

You will receive a new shipment of ARIKAYCE every 4 weeks.



The Lamira® Nebulizer System for ARIKAYCE

This is a one-time shipment.

Plan 14-20 minutes to take your ARIKAYCE treatment

Watch step-by-step instructions on taking ARIKAYCE at ARIKAYCE.com/instructions

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including Boxed Warning, at ARIKAYCE.com.


ARIKAYCE[®]
(amikacin liposome inhalation suspension)
Limited Population

Get 1:1 support through the *Arikares*[®] Support Program

When you start treatment, having great support can make a difference. Support resources can include: your doctor, a loved one, online or live support groups, and the *Arikares Support Program*.

Meet your *Arikares* team

<i>Arikares Coordinator</i>	Your main contact for logistical assistance, insurance and financial information, and 1:1 support throughout your ARIKAYCE journey
<i>Arikares Trainer</i>	A nurse or respiratory therapist who can provide voluntary device training and clinical education

The role of the *Arikares Trainer* is not to provide any medical or treatment advice, or replace the directions that you should receive from your doctor.

Did you know? Insurance covers ARIKAYCE for most people.

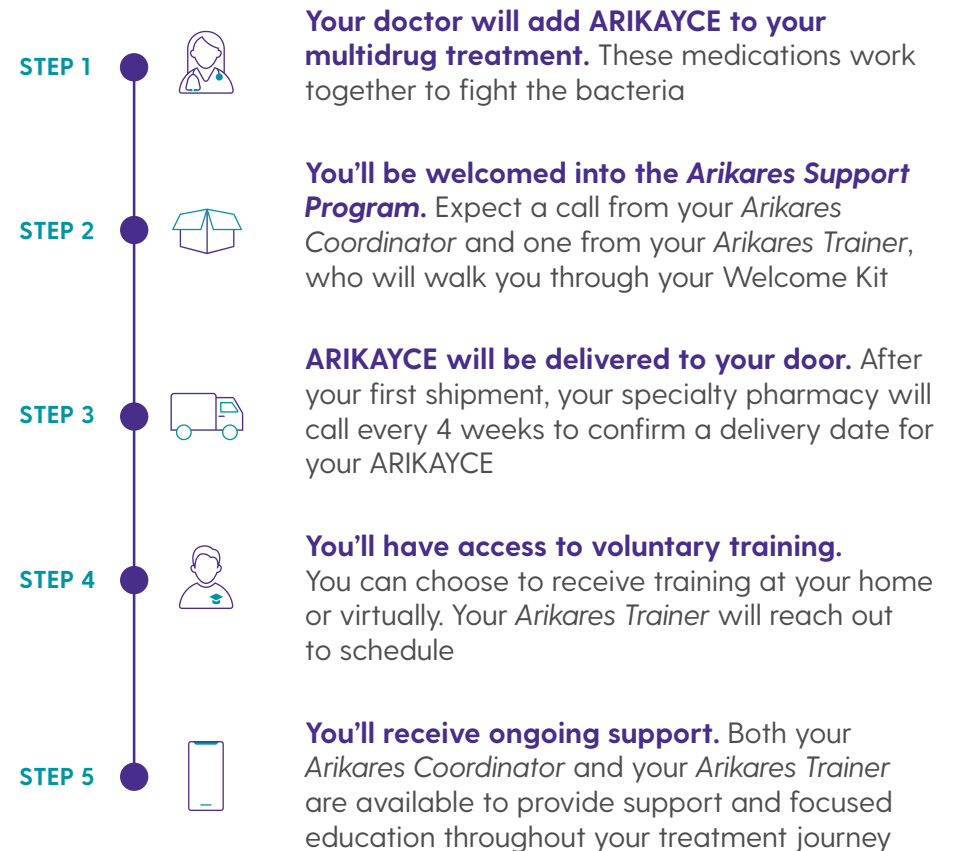
Ask your *Arikares Coordinator* about eligibility for savings and financial support.



Get in touch with an *Arikares Coordinator* at **1-833-ARIKARE (1-833-274-5273)** or **1-973-437-2376**

Here when you need us

Once you are prescribed ARIKAYCE, the *Arikares Support Program* is available to provide additional information and ongoing support. Here's what your treatment journey may look like:



"My Arikares Coordinator keeps a line of communication open. It's great to know I have someone."

-Elisse, a real ARIKAYCE patient

Elisse was compensated for her time.

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including Boxed Warning, at [ARIKAYCE.com](#).

HEAR FROM REAL PATIENTS WITH MAC



"I feel good about the future."

-Lynn, a real ARIKAYCE patient

Lynn was compensated for her time.

Watch real stories at [ARIKAYCE.com/stories](https://www.arikeyce.com/stories)



Arikares[®]
Support Program

Get in touch with an
Arikares Coordinator at **1-833-ARIKARE**
(1-833-274-5273) or **1-973-437-2376**

ARIKAYCE is the **first and only FDA-approved treatment** used in combination with multidrug therapy for adults who still test positive for MAC lung disease after at least 6 months on multidrug treatment alone.

ARIKAYCE was approved by FDA using the Limited Population pathway. This means FDA has approved this drug for a limited and specific patient population, and studies on the drug may have only answered focused questions about its safety and effectiveness.

IMPORTANT SAFETY INFORMATION AND BOXED WARNING

ARIKAYCE is associated with a risk of increased respiratory adverse reactions including allergic inflammation of lungs, coughing up blood, severe breathing problems and worsening of COPD.

Please see additional Important Safety Information throughout and full [Prescribing Information](https://www.arikeyce.com), including Boxed Warning, at [ARIKAYCE.com](https://www.arikeyce.com).



© 2024 Insmed Incorporated. All Rights Reserved. Insmed, ARIKAYCE, and Arikares are trademarks of Insmed Incorporated. All other trademarks are property of their respective owner. PP-ARIK-US-01771

