ARIKAYCE®
(amikacin liposome inhalation suspension)

Limited Population

BE POSITIVE GET MAC-NEGATIVE WITH ARIKAYCE

It's possible to test MAC-negative

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.

MAC=*Mycobacterium avium* complex.

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.

FOR 1 IN 3 PEOPLE, MULTIDRUG TREATMENT ALONE MAY NOT BE ENOUGH

On treatment but still testing positive for MAC?

When you've had regular sputum tests and you're still testing positive for MAC after at least 6 months on multidrug treatment alone, your 6-month treatment assessment is important because that's when experts say your treatment may need to change.

The NTM Treatment Guidelines recommend:

Planning for ongoing monitoring at the start of your multidrug treatment. Getting regular sputum tests (every 1-2 months) is an important part of your MAC treatment plan

Scheduling a 6-month treatment assessment. If you are still testing positive at that time, your treatment may need to change. This is where ARIKAYCE comes in

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

–Judy, a real patient

Judy was compensated for her time.

*Recommendation from 2020 NTM Guidelines.

IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

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

Experts strongly recommend adding ARIKAYCE

The NTM Treatment Guidelines recommend adding ARIKAYCE if:

you have **MAC lung disease**

you've been on 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

†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; NTM=nontuberculous mycobacteria.

IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

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

- **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

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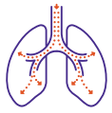
ARIKAYCE targets the MAC infection directly in your lungs

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



Once inside the lungs, the liposomes enter the body's cells (called macrophages) and release the antibiotic to fight the MAC bacteria where they live

IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

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

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

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 patient

Elisse was compensated for her time.

Watch ARIKAYCE in action at ARIKAYCE.com/action

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

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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 got 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 and in overall health, daily life, and perceived well-being in people with lung disease (as measured by a questionnaire)*

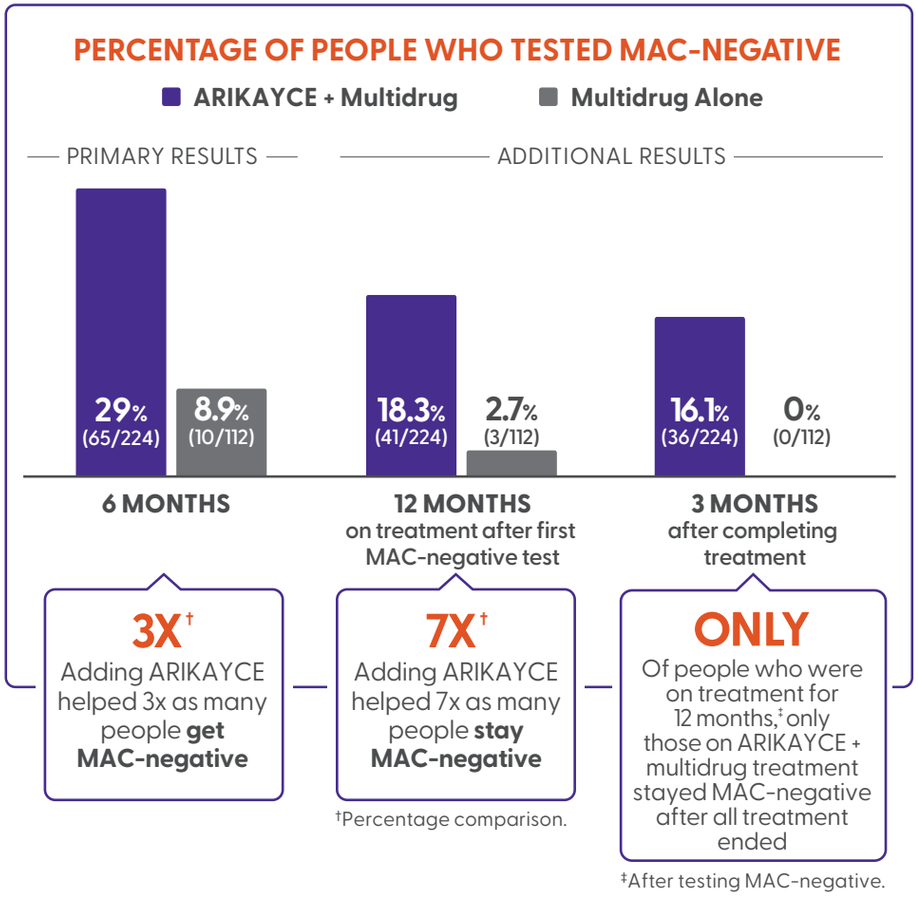
*6-minute walk test and St George's Respiratory Questionnaire.

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 get MAC-negative and stay MAC-negative even after completing treatment



†Percentage comparison.

‡After testing MAC-negative.

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.

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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 in combination with a multidrug treatment:

Side effect	% of people
changes to your voice and hoarseness	48%
cough	40%
muscle pain	18%
sore throat	18%
fatigue	16%
diarrhea	13%
nausea	12%

Side effect	% of people
headache	10%
fever	8%
decreased weight	7%
vomiting	7%
rash	6%
increased sputum	6%
chest discomfort	5%

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

Talking to your doctor about possible side effects ahead of time can **help you stay on treatment as prescribed**.

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.

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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 Insmed Incorporated. Insmed 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

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Map out your MAC treatment plan with your doctor

Keeping the lines of communication open with your doctor and establishing your ARIKAYCE treatment plan is important as you work toward your treatment goal of being MAC-negative.

Important things to discuss with your doctor:

Treatment goals: Set treatment goals with your doctor to stay motivated while taking ARIKAYCE. Ask your doctor when to expect sputum tests and how long you could be on treatment

Preparing for possible side effects: Planning ahead of time can help you stay on treatment as prescribed. In the ARIKAYCE study*, the most frequent side effects were first reported within the initial months of taking ARIKAYCE. Ask your doctor about possible side effects and how they may be managed

Staying on treatment as prescribed: If you've tested MAC-negative, it's important to keep partnering with your doctor and taking your treatment as prescribed

Length of treatment: In the NTM Treatment Guidelines, experts recommend staying on treatment for at least 1 year after testing MAC-negative. This is to help make sure the MAC bacteria are cleared from your lungs

*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 people added ARIKAYCE to their multidrug treatment and 112 continued to take a multidrug treatment alone. 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. Improvement in the distance people walked after 6 minutes (the 6-minute walk test) and in overall health, daily life, and perceived well-being in people with lung disease (as measured by a questionnaire called the St George's Respiratory Questionnaire) were additional objectives.

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)

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

IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

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.**

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Get 1:1 support throughout your ARIKAYCE treatment journey

When you start your treatment, having great support can make a difference. Support resources can include your doctor, a loved one, online or live support groups, and the *inLighten*™ *Patient Support* program.

Meet your *inLighten* team

inLighten Coordinator	Your main contact for arranging prescription deliveries, insurance and financial information, and 1:1 support throughout your treatment journey.
inLighten Educator	With their background in respiratory care*, *inLighten Educators* can provide voluntary in-home or virtual device training and dedicated support and education throughout your treatment journey.

*It is not the role of the *inLighten Educator* to provide medical or treatment advice or replace the instructions you receive from your healthcare provider.

SUPPORT

Insurance covers treatment for most people. There are also savings and financial support resources available for eligible patients. Get in touch with your *inLighten Coordinator* at **833-LIGHT-00 (833-544-4800) Monday – Friday, 8 AM – 8 PM Eastern Time**.

Here for you along the journey

Once you are prescribed ARIKAYCE, the *inLighten Patient Support* program is available to provide ongoing support. Here's what your treatment journey with *inLighten* may look like:

STEP 1 **Enroll in *inLighten*.** You can enroll with your doctor, by visiting enroll.inlightensupport.com, or calling 833-LIGHT-00 (833-544-4800) Monday through Friday, 8 AM – 8 PM Eastern Time.

STEP 2 **Expect a call from your *inLighten* Team** 833-LIGHT-00 (833-544-4800). Your *inLighten Coordinator* will introduce the program and walk you through next steps. Your *inLighten Educator* will provide an overview of the treatment.

STEP 3 **ARIKAYCE will be delivered to your door.** Your specialty pharmacy will call each month to confirm shipment of your treatment. Please make sure to answer or return calls from your specialty pharmacy.

STEP 4 **You can schedule voluntary training on how to take ARIKAYCE.** You can receive training at your home or virtually. Your *inLighten Educator* will reach out to schedule.

STEP 5 **You'll receive ongoing support.** Both your *inLighten Coordinator* and your *inLighten Educator* are available to provide support and focused education throughout your treatment journey.

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

–Elisse, a real 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 patient

Lynn was compensated for her time.

Watch real stories at ARIKAYCE.com/stories

ARIKAYCE (amikacin liposome inhalation suspension) Limited Population | inLighten™ Patient Support

Get in touch with an *inLighten Coordinator* at
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