

Establishing a treatment plan with your doctor

Now that you've been diagnosed with *Mycobacterium avium* complex (MAC) lung disease, establishing a treatment plan with your doctor can be an important first step for your health.

Why a treatment plan is important

A treatment plan is how you and your doctor can set treatment goals and track your progress toward achieving them.

Establishing a treatment plan with your doctor will also help you know what to expect along your health journey. You will be able to work closely with your doctor to get answers to questions, understand how to take your medication, establish a medication routine, and more.



KEEP IN MIND:

- An important goal of therapy is testing MAC-negative
- Talk to your doctor about an overarching treatment plan that can include follow-up visits, progress tracking, and how to manage any side effects

Important milestones

The updated 2020 NTM Treatment Guidelines now recommend adding ARIKAYCE to a multidrug regimen for MAC lung disease patients who continue to test positive after at least 6 months of a multidrug regimen alone. These guidelines were created by leading scientific communities to provide recommendations and standards for nontuberculous mycobacterial (NTM) lung disease treatment.

Setting milestones with your doctor should be a key part of your treatment journey.

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| Starting treatment | Treatment guidelines recommend a multidrug regimen of at least 3 antibiotics after MAC lung disease is diagnosed. |
| After 1 to 5 months | Schedule regular doctor appointments to get your sputum tested every 1 to 2 months. |
| At 6 months | <p>Assess treatment success at 6 months—have you tested MAC-negative?</p> <ul style="list-style-type: none"> – If you are still testing MAC-positive after at least 6 months of treatment, you and your doctor may want to add another option called ARIKAYCE <p>What is ARIKAYCE? ARIKAYCE is the first and only FDA-approved treatment option designed specifically to treat MAC lung disease as part of a multidrug treatment plan in adults who continue to test positive after at least 6 months of a multidrug regimen alone. Talk to your doctor about whether ARIKAYCE is the right fit for you.</p> |
| At 12+ months | It is recommended that you stay on a multidrug regimen for a minimum of 12 months after testing negative for MAC to ensure the MAC bacteria is cleared from your lungs. |

IMPORTANT SAFETY INFORMATION

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

Please see additional Important Safety Information throughout and full Prescribing Information, including Boxed Warning, at ARIKAYCE.com.



Understanding and managing side effects

Everyone responds to treatment differently—and during treatment, you may experience side effects. Before you start any treatment, talk to your doctor about possible side effects.

Here's a good conversation starter:

- What side effects should I be aware of? What should I do if I experience any?

Once you start treatment, keep track of any side effects you experience. Your doctor may have strategies to help you manage them.



Keep track of treatment progress

For a treatment plan to work, it's important to stay committed to your treatment regimen, make it part of your daily routine, and communicate with your doctor regularly. Here are some ways you can do that:

Make a schedule:

- Talk to your doctor about your daily schedule and activities so the two of you can better figure out the best time of day to take your medication, as well as make any adjustments if there are changes to your treatment plan

Set goals:

- Stay committed to your treatment by creating meaningful treatment goals, like ones that can directly affect your well-being and comfort

Let your doctor be your health partner:

- Remember, your doctor is there to help you along your treatment journey, so be sure to keep the lines of communication open
 - Make note of how you're feeling or any questions you may have and share them during your next visit

Notes

IMPORTANT SAFETY INFORMATION (cont'd)

- **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
- **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.

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
- 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

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IMPORTANT SAFETY INFORMATION (cont'd)

- 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

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)
- **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
- **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.

What is ARIKAYCE?

ARIKAYCE is a prescription medicine used to treat adults with refractory (difficult to treat) *Mycobacterium avium* complex (MAC) lung disease as part of a combination antibacterial drug treatment plan (regimen).

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

This product 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.

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