ARIKAYCE®
(amikacin liposome inhalation suspension)
590 mg/8.4 mL

Limited Population

Counseling your patients on the ARIKAYCE treatment journey

A guide for healthcare professionals and staff

INDICATION

LIMITED POPULATION: ARIKAYCE® is indicated in adults, who have limited or no alternative treatment options, for the treatment of *Mycobacterium avium* complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. As only limited clinical safety and effectiveness data for ARIKAYCE are currently available, reserve ARIKAYCE for use in adults who have limited or no alternative treatment options. This drug is indicated for use in a limited and specific population of patients.

This indication is approved under accelerated approval based on achieving sputum culture conversion (defined as 3 consecutive negative monthly sputum cultures) by Month 6. Clinical benefit has not yet been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Limitation of Use: ARIKAYCE has only been studied in patients with refractory MAC lung disease defined as patients who did not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. The use of ARIKAYCE is not recommended for patients with non-refractory MAC lung disease.

IMPORTANT SAFETY INFORMATION AND BOXED WARNING

WARNING: RISK OF INCREASED RESPIRATORY ADVERSE REACTIONS
ARIKAYCE has been associated with an increased risk of respiratory adverse reactions, including hypersensitivity pneumonitis, hemoptysis, bronchospasm, and exacerbation of underlying pulmonary disease that have led to hospitalizations in some cases.

Please see additional Important Safety Information, including Boxed Warning, throughout and enclosed full Prescribing Information.

Counseling patients for what's ahead

This is a guide for healthcare professionals counseling patients who remain culture positive following ≥6 months of multidrug therapy about adding ARIKAYCE to multidrug therapy and the journey to getting and staying culture negative.

Patients, frustrated when multidrug therapy fails, may take comfort in knowing they are not alone:

Nearly one-third of patients remain culture positive after ≥6 months of multidrug therapy.[1-3†]

With a better understanding of what to expect when starting ARIKAYCE, your patients may be better prepared for the treatment journey ahead.[4,5]

The 2020 NTM Treatment Guidelines recommend continuing MAC treatment for 12 months after initial culture conversion.[5]

ARIKAYCE is the first and only FDA-approved treatment used in combination with multidrug therapy for adults with MAC lung disease remaining culture positive after ≥6 months of multidrug treatment.[6]

Adding ARIKAYCE helped patients get converted and stay converted

- In a clinical trial of adults who remained culture positive following ≥6 months of multidrug therapy, adding ARIKAYCE helped[6-8]:

3x‡ **as many patients get converted by Month 6 (29.0%; n=65/224) vs those on multidrug therapy alone (8.9%; n=10/112)**

7x‡ **as many patients stay converted at 12 months after initial conversion (18.3%; n=41/224) vs those on multidrug therapy alone (2.7%; n=3/112)**

- Of patients who remained on therapy for 12 months after culture conversion, **only those on ARIKAYCE + multidrug therapy** (16.1%; n=36/224) **stayed culture negative after all treatment ended**[6-8]

In the CONVERT trial, the endpoints of the change from baseline in 6MWT distance and SGRQ did not demonstrate clinical benefit at Month 6.[6]

For more information about culture conversion results for ARIKAYCE, scan here or visit ARIKAYCEhcp.com.

IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

Hypersensitivity Pneumonitis has been reported with the use of ARIKAYCE in the clinical trials. Hypersensitivity pneumonitis (reported as allergic alveolitis, pneumonitis, interstitial lung disease, allergic reaction to ARIKAYCE) was reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (3.1%) compared to patients treated with background regimen alone (0%). Most patients with hypersensitivity pneumonitis discontinued treatment with ARIKAYCE and received treatment with corticosteroids. If hypersensitivity pneumonitis occurs, discontinue ARIKAYCE and manage patients as medically appropriate.

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Getting patients started on ARIKAYCE

ARIKAYCE is a once-daily oral inhalation with at-home administration.[6,9] ARIKAYCE should be taken as part of a multidrug antibacterial regimen.[6] The entire healthcare team can play a role in helping patients establish a routine for taking ARIKAYCE by answering their questions and sharing information.

The following self-administration tips may be helpful to patients:

- Establish a regular time of day to take ARIKAYCE
- Establish a regular place to take ARIKAYCE, where the patient can sit upright by a clean, flat surface with proximity to a power outlet for plugging in the Lamira® Nebulizer System[6,9]
- Prior to first use, and subsequently after each use, the nebulizer handset must be cleaned and disinfected[9]
- Patients who use a bronchodilator should use it prior to taking ARIKAYCE[6]

A basic understanding of the time frame required for taking ARIKAYCE—including cleaning and disinfecting the nebulizer handset after each use—can help patients successfully establish a routine. Self-administration time may vary and could take up to **20 minutes.**[9]

6MWT=6-minute walk test; MAC=*Mycobacterium avium* complex; NTM=nontuberculous mycobacteria; SGRQ=St George's Respiratory Questionnaire.

For more information on how to take ARIKAYCE, including a video with step-by-step instructions, scan here or visit ARIKAYCEhcp.com.

†Data from 3 separate studies. A systematic review using ATS-recommended multidrug therapy found that 34% of patients (N=494) did not achieve culture conversion after ≥12 months.[3] A retrospective cohort study using daily and intermittent multidrug therapy found that 24% of daily therapy patients (n=24/99) and 33% of intermittent-therapy patients (n=39/118) did not achieve culture conversion after 12 months.[1] And, lastly, a post hoc analysis of a 3rd study found that 24% of patients (n=113/470) did not achieve culture conversion within 12 months of treatment.[2]

‡Percentage comparison.

IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

Hemoptysis has been reported with the use of ARIKAYCE in the clinical trials. Hemoptysis was reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (18.4%) compared to patients treated with background regimen alone (13.4%). If hemoptysis occurs, manage patients as medically appropriate.

Bronchospasm has been reported with the use of ARIKAYCE in the clinical trials. Bronchospasm (reported as asthma, bronchial hyperreactivity, bronchospasm, dyspnea, dyspnea exertional, prolonged expiration, throat tightness, wheezing) was reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (28.7%) compared to patients treated with background regimen alone (10.7%). If bronchospasm occurs during the use of ARIKAYCE, treat patients as medically appropriate.

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Discussing common side effects and possible management techniques

An upfront conversation can inform patients on what they may experience during treatment.

To facilitate an ongoing conversation, ask patients to keep track of their side effects so you can share further information as needed.

There are potential management techniques for respiratory adverse events (AEs) that may be helpful for patients taking ARIKAYCE.[4,6] A downloadable **Patient Adverse Event Tear Pad** to help patients know what to expect from treatment with ARIKAYCE is available. Scan the QR code below or visit **www.ARIKAYCEhcp.com/resources.**

- NTM Guidelines suggest that patients who have a plan for managing side effects may have a better chance of taking treatment as prescribed[5]

Some of the most common AEs (≥5% of ARIKAYCE-treated patients) included dysphonia, cough, bronchospasm, hemoptysis, and musculoskeletal pain.[6]

To download the Patient Adverse Events Tear Pad, scan here or visit ARIKAYCEhcp.com.

IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

Exacerbations of underlying pulmonary disease have been reported with the use of ARIKAYCE in the clinical trials. Exacerbations of underlying pulmonary disease (reported as chronic obstructive pulmonary disease (COPD), infective exacerbation of COPD, infective exacerbation of bronchiectasis) have been reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (15.2%) compared to patients treated with background regimen alone (9.8%). If exacerbations of underlying pulmonary disease occur during the use of ARIKAYCE, treat patients as medically appropriate.

Anaphylaxis and Hypersensitivity Reactions: Serious and potentially life-threatening hypersensitivity reactions, including anaphylaxis, have been reported in patients taking ARIKAYCE. Signs and symptoms include acute onset of skin and mucosal tissue hypersensitivity reactions (hives, itching, flushing, swollen lips/tongue/uvula), respiratory difficulty (shortness of breath, wheezing, stridor, cough), gastrointestinal symptoms (nausea, vomiting, diarrhea, crampy abdominal pain), and cardiovascular signs and symptoms of anaphylaxis (tachycardia, low blood pressure, syncope, incontinence, dizziness). Before therapy with ARIKAYCE is instituted, evaluate for previous hypersensitivity reactions to aminoglycosides. If anaphylaxis or a hypersensitivity reaction occurs, discontinue ARIKAYCE and institute appropriate supportive measures.

Ototoxicity has been reported with the use of ARIKAYCE in the clinical trials. Ototoxicity (including deafness, dizziness, presyncope, tinnitus, and vertigo) were reported with a higher frequency in patients treated with ARIKAYCE plus background regimen (17%) compared to patients treated with background regimen alone (9.8%). This was primarily driven by tinnitus (8.1% in ARIKAYCE plus background regimen vs 0.9% in the background regimen alone arm) and dizziness (6.3% in ARIKAYCE plus background regimen vs 2.7% in the background regimen alone arm). Closely monitor patients with known or suspected auditory or vestibular dysfunction during treatment with ARIKAYCE. If ototoxicity occurs, manage patients as medically appropriate, including potentially discontinuing ARIKAYCE.

Please see additional Important Safety Information, including Boxed Warning, throughout and enclosed full Prescribing Information.

The *inLighten™ Patient Support* program offers enrolled patients ongoing support and information

Once your patient is prescribed ARIKAYCE, *inLighten* is available to them. Your patient will receive a **Welcome Pack** and a call from an *inLighten Coordinator* to discuss next steps and answer questions.

When prescribed ARIKAYCE and enrolled in *inLighten*

Patients will receive a call from their *inLighten* team and specialty pharmacy. *inLighten Coordinators* serve as a dedicated resource by helping the patient through their treatment initiation, including:

- Keeping them informed of the payer approval process
- Understanding the role of the specialty pharmacy
- Providing information on the resources and training available as patients go through their journey

***inLighten Coordinators* keep patients informed of next steps and answer any questions patients may have related to getting their delivery of ARIKAYCE.**

When starting ARIKAYCE

Your patients will be sent a Welcome Pack in the mail after enrollment in *inLighten* that includes important and helpful information about getting started with ARIKAYCE.

Patients will also receive 2 separate boxes:

- The **28-day ARIKAYCE Kit**, which contains ARIKAYCE
- The **Getting Started Kit**, which includes the **Lamira® Nebulizer System**

While continuing ARIKAYCE

inLighten can provide patients with voluntary live or virtual device training on how to set up the nebulizer and how to take ARIKAYCE.

To assist patients in enrolling in *inLighten*, scan here or visit ARIKAYCEhcp.com.

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Tips for helping patients starting on ARIKAYCE: what to expect

Share your reason for adding ARIKAYCE and what they can expect

Connect patients with the additional support that's available through *inLighten*

- ☐ Complete the ***inLighten* Enrollment Form** to prescribe ARIKAYCE and give your patients the opportunity to enroll in *inLighten*
- ☐ Fill out the fields on the form, including your signature, and ask your patient to sign
- ☐ **Remember to get your patient's signatures on the Enrollment Form.** One signature gets your patient's consent to submit their information, and the other signature gives them access to patient support services
- ☐ The Enrollment Form may also be submitted online at enroll.inlightensupport.com

inLighten™ Patient Support

IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

Nephrotoxicity was observed during the clinical trials of ARIKAYCE in patients with MAC lung disease but not at a higher frequency than background regimen alone. Nephrotoxicity has been associated with the aminoglycosides. Close monitoring of patients with known or suspected renal dysfunction may be needed when prescribing ARIKAYCE.

Neuromuscular Blockade: Patients with neuromuscular disorders were not enrolled in ARIKAYCE clinical trials. Aminoglycosides may aggravate muscle weakness by blocking the release of acetylcholine at neuromuscular junctions. Closely monitor patients with known or suspected neuromuscular disorders, such as myasthenia gravis. If neuromuscular blockade occurs, it may be reversed by the administration of calcium salts but mechanical respiratory assistance may be necessary.

Embryo-Fetal Toxicity: Aminoglycosides can cause fetal harm when administered to a pregnant woman. Aminoglycosides, including ARIKAYCE, may be associated with total, irreversible, bilateral congenital deafness in pediatric patients exposed *in utero*. Patients who use ARIKAYCE during pregnancy, or become pregnant while taking ARIKAYCE should be apprised of the potential hazard to the fetus.

Contraindications: ARIKAYCE is contraindicated in patients with known hypersensitivity to any aminoglycoside.

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Help patients prepare for possible side effects[5]

NTM Guidelines suggest that patients who have a plan for managing side effects may have a better chance of taking treatment as prescribed.

Rapid identification of AEs may possibly:

- Help manage the risks of treatment
- Help improve the chances of treatment completion

Continue to schedule regular follow-ups[5]

- Guidelines recommend sputum cultures every 1-2 months to document when cultures become negative
- Guidelines also recommend continuing MAC† treatment for 12 months after culture conversion

†In patients with macrolide-susceptible MAC pulmonary disease.[5]

IMPORTANT SAFETY INFORMATION AND BOXED WARNING (cont'd)

Most Common Adverse Reactions: The most common adverse reactions in Trial 1 at an incidence ≥5% for patients using ARIKAYCE plus background regimen compared to patients treated with background regimen alone were dysphonia (48% vs 2%), cough (40% vs 17%), bronchospasm (29% vs 11%), hemoptysis (18% vs 13%), musculoskeletal pain (18% vs 9%), upper airway irritation (18% vs 2%), ototoxicity (17% vs 10%), fatigue and asthenia (16% vs 10%), exacerbation of underlying pulmonary disease (15% vs 10%), diarrhea (13% vs 5%), nausea (12% vs 4%), headache (10% vs 5%), pneumonia (9% vs 9%), pyrexia (8% vs 5%), decreased weight (7% vs 1%), vomiting (7% vs 4%), rash (6% vs 1%), change in sputum (6% vs 1%), and chest discomfort (5% vs 3%).

Drug Interactions: Avoid concomitant use of ARIKAYCE with medications associated with neurotoxicity, nephrotoxicity, and ototoxicity. Some diuretics can enhance aminoglycoside toxicity by altering aminoglycoside concentrations in serum and tissue. Avoid concomitant use of ARIKAYCE with ethacrynic acid, furosemide, urea, or intravenous mannitol.

Overdosage: Adverse reactions specifically associated with overdose of ARIKAYCE have not been identified. Acute toxicity should be treated with immediate withdrawal of ARIKAYCE, and baseline tests of renal function should be undertaken. Hemodialysis may be helpful in removing amikacin from the body. In all cases of suspected overdosage, physicians should contact the Regional Poison Control Center for information about effective treatment.

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Find out more about patient counseling

Scan here to watch Dr Juzar Ali share his insights about the goals of counseling and the key educational points.

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References: 1. Jeong BH, et al. *Am J Respir Crit Care Med*. 2015;191(1):96-103. doi:10.1164/rccm.201408-1545OC **2.** Moon SM, et al. *Eur Respir J*. 2019;53(5):1801636. doi:10.1183/13993003.01636-2018 **3.** Diel R, et al. *Chest*. 2018;153(4):888-921. doi:10.1016/j.chest.2018.01.024 **4.** Swenson C, et al. *Open Forum Infect Dis*. 2020:7(4). doi:10.1093/ofid/ofaa079 **5.** Daley CL, et al. *Clin Infect Dis*. 2020;71(4):e1-e36. doi:10.1093/cid/ciaa241 **6.** ARIKAYCE [package insert]. Bridgewater, NJ: Insmed Incorporated; 2023. **7.** Griffith DE, et al. *Am J Respir Crit Care Med*. 2018;198(12):1559-1569. doi:10.1164/rccm.201807-1318OC **8.** Griffith DE, et al. *Chest*. 2021;160(3):831-842. doi:10.1016/j.chest.2021.03.070 **9.** Lamira Nebulizer System instructions for use. Midlothian, VA: PARI Respiratory Equipment, Inc; 2021.

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