Arikares Support Program Enrollment Form and Prescription (Rx)

Arikares®

To get started, submit all pages of this form through
Fax: 1-800-604-6027 or **E-mail:** enrollment@arikares.com

Questions?
Phone: **1-833-ARIKARE** (1-833-274-5273)
Alternate Phone: 1-973-437-2376

Please complete all fields on page 1 and 3 to prevent any delays and include scanned copies of both sides of your insurance card (fields marked with an asterisk [*] are mandatory/required).

PATIENT INFORMATION

*Patient First Name: _____ *Patient Last Name: _____ *MI: _____

*DOB: _____ *Gender: ☐ Male ☐ Female Last 4 of SSN: _____

*Shipping Address: _____ *City: _____

*State: _____ *ZIP: _____ *Home Phone: _____ *Cell Phone: _____

E-mail: _____

Applicable Contact Method(s): (check all that apply) ☐ Home ☐ Cell ☐ E-mail ☐ Text

Preferred Time to Contact: ☐ Morning ☐ Afternoon ☐ Evening

Preferred Contact Language: ☐ English ☐ Spanish ☐ Other: _____

Authorized Alternate Contact: _____

Alternate Contact Phone: _____ Relationship to Patient: _____

Prescription Insurance Information *(Please Send a Copy of Your Insurance Card)*

*Prescription Coverage Plan Name: _____

Beneficiary/Cardholder: _____ Relationship to Cardholder: _____

*Primary Rx Insurance ID #: _____ *Group #: _____

*BIN: _____ *PCN: _____ *Phone: _____

*Primary Rx Plan Type: ☐ Private/Commercial ☐ Medicare Part D ☐ Medicaid ☐ TRICARE ☐ Other

Secondary Rx Plan Name: _____

Beneficiary/Cardholder: _____ Relationship to Cardholder: _____

Secondary Rx Insurance ID #: _____ Group #: _____

BIN: _____ PCN: _____ Phone: _____

Secondary Rx Plan Type: ☐ Private/Commercial ☐ Medicare Part D ☐ Medicaid ☐ TRICARE ☐ Other

Patient Does Not Have Insurance ☐

Patient Authorization Signature

☐ I have reviewed and understand this form.

Information Disclosure – I have read and understand the Patient Authorization on page 2, and I agree to allow My Information (as defined in the Patient Authorization) to be used and shared as described in the Authorization.

***Patient Signature:** _____ ***Date:** _____

Program Enrollment – By signing below, I agree to enroll in the *Arikares Support Program* and verify that the information in the "Patient Information" section of this form is accurate and complete.

***Patient Signature:** _____ ***Date:** _____

Please see Indication and Important Safety Information for ARIKAYCE, including Boxed Warning, on page 4. Please see accompanying full Prescribing Information.

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

By signing the Patient Authorization block on page 1, I authorize my healthcare providers, including the pharmacies I use, and my health insurance plan(s) to disclose my personal information, including information about me (eg, my name, address) and my health, including my finances, insurance, prescriptions, pharmacy fills/claims, and medical condition ("My Information") to Insmed (the manufacturer of ARIKAYCE® [amikacin liposome inhalation suspension]) and its affiliates, agents, and contractors, including the administrators of the Insmed *Arikares® Support Program*, the dispensing pharmacies of Insmed products, and any other person or entity assisting Insmed in the administration of the *Arikares* Program (collectively, the "Insmed *Arikares* Team"), for the purposes listed below:

1. To investigate, verify, and determine my insurance coverage for ARIKAYCE
2. To provide financial assistance, and support to facilitate access to ARIKAYCE and the Lamira® System as prescribed by my treating physician
3. To facilitate a voluntary training session educating on device use and successful treatment initiation
4. To determine my initial and continuing eligibility for other assistance programs
5. To contact me by phone, mail, e-mail (if my e-mail address was provided), cell phone, or text message (if my cell phone was provided) to request further information, discuss the application process, administer the Program, evaluate treatment progress and/or the effectiveness of the Program, and to conduct market research
6. For Insmed's internal business purposes of continuous improvement, including ongoing quality control
7. To help ensure the accuracy and completeness of my applications
8. To send me marketing information, offers, and educational materials related to MAC (*Mycobacterium avium* complex) lung disease and/or ARIKAYCE

I understand that my pharmacy provider may receive remuneration from Insmed in exchange for the health information provided and/or for any therapy support services provided to me. I also understand that once My Information has been disclosed under this Authorization, federal privacy laws may no longer protect it and that it may be subject to further disclosure. I specifically authorize the Insmed Team to use and disclose My Information for the purposes listed above. I further understand that if I decline to sign this Authorization, that will not affect my eligibility for health plan benefits and treatment by my healthcare providers, but I will not have access to the education and services available through the *Arikares Support Program*. I understand that I may revoke this Authorization at any time by calling **1-833-274-5273** (alternate phone 1-973-437-2376) or writing to Insmed Incorporated, Attn: Arikares, 700 US Highway 202/206, Bridgewater, NJ 08807. If I do revoke this Authorization, the Insmed *Arikares* Team will stop accessing, using, and disclosing My Information thereafter, but the uses and disclosures previously made in reliance on the Authorization will not be deemed invalid. This Authorization expires ten (10) years from the date of my Program Enrollment signature on page 1, unless specified or mandated to be shorter by applicable state law. I understand that I am entitled to a copy of this Authorization once signed.

Please see Indication and Important Safety Information for ARIKAYCE, including Boxed Warning, on page 4.
Please see accompanying full Prescribing Information.

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HEALTHCARE PROFESSIONAL & PRESCRIPTION INFORMATION

*Prescriber First Name: _____ *Prescriber Last Name: _____

*Practice Name: _____ Specialty: _____

*Address: _____ *City: _____ *State: _____ *ZIP: _____

*Phone: _____ *Fax: _____ *NPI #: _____

Office Contact Name: _____ Office Contact Phone: _____

Office Contact E-mail: _____

If Applicable, Check Appropriate Box for Specialty Pharmacy Preference:

☐ No Preference ☐ Maxor Specialty (IV Solutions/Pharmaceutical Specialties)
☐ Kroger Specialty Pharmacy ☐ Orsini Specialty Pharmacy ☐ PANTHERx Specialty Pharmacy

Official Prescription Information

*Patient First Name: _____ *Patient Last Name: _____ *DOB: _____

*Product: ☐ ARIKAYCE® (amikacin liposome inhalation suspension)

*Dosing Info: ☐ Once-Daily 590 mg/8.4 mL

*Quantity: ☐ 28-Day Supply: 28-Vial Pack (28 Vials of Medication, 4 Aerosol Heads, and 1 Handset)
(First Shipment Includes Lamira® System)

*# of Refills: _____

New York prescribers, please submit prescription on an original NY State prescription blank. The prescriber is to comply with his or her state-specific form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to the prescriber.

***Substitution Permitted?** ☐ Yes ☐ No

Prescriber Certification

I certify that the above therapy is medically necessary and that the information provided is accurate to the best of my knowledge. I certify that I am the prescriber who has prescribed ARIKAYCE to the previously identified patient and that I provided the patient with a description of the *Arikares Support Program*. I authorize the *Arikares Support Program* to act on my behalf for the purposes of transmitting this prescription to the appropriate pharmacy.

***Prescriber Signature:** _____ ***Date:** _____
No stamped signatures accepted

Special Instructions:

Please see Indication and Important Safety Information for ARIKAYCE, including Boxed Warning, on page 4. Please see accompanying full Prescribing Information.

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

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

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.

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 a 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.

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 (17.9%) compared to patients treated with a background regimen alone (12.5%). 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 a background regimen alone (10.7%). If bronchospasm occurs during the use of ARIKAYCE, treat patients as medically appropriate.

Exacerbations of underlying pulmonary disease has 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 (14.8%) 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 (7.6% 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.

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. Patients with known or suspected neuromuscular disorders, such as myasthenia gravis, should be closely monitored since aminoglycosides may aggravate muscle weakness by blocking the release of acetylcholine at neuromuscular junctions.

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.

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 (47% vs 1%), cough (39% vs 17%), bronchospasm (29% vs 11%), hemoptysis (18% vs 13%), ototoxicity (17% vs 10%), upper airway irritation (17% vs 2%), musculoskeletal pain (17% vs 8%), fatigue and asthenia (16% vs 10%), exacerbation of underlying pulmonary disease (15% vs 10%), diarrhea (13% vs 5%), nausea (12% vs 4%), pneumonia (10% vs 8%), headache (10% vs 5%), pyrexia (7% vs 5%), vomiting (7% vs 4%), rash (6% vs 2%), decreased weight (6% vs 1%), change in sputum (5% 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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