ARIKAYCE Prescription

Fax: (800) 604-6027 or email: enrollment@inlightensupport.com

To prevent delays, please:
1. Complete all required fields (marked with an asterisk) on pages 1 and 3
2. Include scanned copies of both sides of the patient's pharmacy insurance card(s)

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

inLighten® Patient Support

HEALTHCARE PROFESSIONAL & PRESCRIPTION INFORMATION

Patient Information:

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

*DOB: _____ *Gender: ☐ Male ☐ Female ☐ Non-Binary ☐ Unknown

*Physical Address (no PO boxes): _____

*Physical City: _____ *Physical State: _____ *Physical ZIP: _____ *Mobile Phone: _____

Prescriber Information:

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

*Practice Name: _____ Specialty: _____

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

*Phone: _____ Extension Line: _____ *Fax: _____ *NPI #: _____

Office Contact Name: _____ Office Contact Phone: _____

Office Contact Email: _____ Best Time to Contact Office: ☐ AM ☐ PM

This **Prescription does not need** to be sent to a pharmacy because it was already sent directly to a:
☐ SP checked below ☐ VA pharmacy ☐ 340B entity

ARIKAYCE is fulfilled by 3 in-network pharmacies. Check box below to indicate preference. ☐ No Preference
☐ Amber Specialty Pharmacy ☐ PANTHERx RARE Pharmacy ☐ VytlOne Specialty Pharmacy

Current medications: _____

Known drug allergies: _____

Official Prescription Information

Product: ARIKAYCE® (amikacin liposome inhalation suspension)

Quantity: 28-Day Supply: 28-Vial Pack
(28 Vials of Medication, 4 Aerosol Heads, and 1 Handset)
(First shipment includes Lamira® system)

Dosing Info: Once-daily 590 mg/8.4 mL

*Number 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. By submitting this form, I certify that I am the prescriber who has prescribed ARIKAYCE to the previously identified patient, that the patient authorized the disclosure of their personal health information to Insmed, that I provided the patient with a description of the *inLighten® Patient Support* program, and that the patient has given permission to be contacted by Insmed regarding the *inLighten Patient Support* program. I authorize the *inLighten Patient Support* program to act on my behalf for the purposes of transmitting this prescription to the appropriate pharmacy.

Prescriber Signature _____ ***Date** _____
No stamped or electronic signatures accepted

Special Instructions

☐ Pre-treatment with inhaled bronchodilator due to history of hyperreactive airway disease

Please see Indication and Important Safety Information for ARIKAYCE, including Boxed Warning, on page 2 and accompanying full Prescribing Information.

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Questions?
Phone: **833-LIGHT-00 (833-544-4800)**

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.

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.

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.

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.

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.

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.

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.

Please see accompanying full Prescribing Information.

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Patient Support Program Enrollment Form

Fax: (800) 604-6027 or email: enrollment@inlightensupport.com

To prevent delays, please:
1. Complete all required fields (marked with an asterisk) on pages 1 and 3
2. Include scanned copies of both sides of the patient's pharmacy insurance card(s)

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

inLighten® Patient Support

PATIENT INFORMATION

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

*DOB: _____ *Gender: ☐ Male ☐ Female ☐ Non-Binary ☐ Unknown

*Physical Address (no PO boxes): _____

*Physical City: _____ *Physical State: _____ *Physical ZIP: _____

*Mailing Address: _____ ☐ Same as Physical Address

*Mailing City: _____ *Mailing State: _____ *Mailing ZIP: _____

*Mobile Phone: _____ Home Phone: _____ Patient Email: _____

Preferred Time to Contact: ☐ Morning ☐ Afternoon ☐ Evening

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

Authorized Alternate Contact (or parent/guardian) First Name: _____ Last Name: _____

Alternate Contact Phone: _____ Relationship to Patient: _____

Authorization for Use and Disclosure of My Health Information: I have read and agree to the Authorization for Use and Disclosure of My Health Information on page 4. By signing below, I authorize the disclosure of my PHI to the *inLighten Patient Support* program as described in the Authorization for Use and Disclosure of My Health Information on page 4.

***Patient Signature 1** _____ ***Date** _____

PATIENT / LEGAL REPRESENTATIVE

Patient Support Program Enrollment and Data Collection Consent: I have read and agree to the Patient Support Program Enrollment and Data Collection Consent on page 4. By signing below, I agree to enroll in the *inLighten Patient Support* program and consent to processing of my Health Information as described in the Patient Support Program Enrollment and Data Collection Consent on page 4.

***Patient Signature 2** _____ ***Date** _____

PATIENT / LEGAL REPRESENTATIVE

If signed by legal representative:

Printed name: _____ Relationship to patient: _____

Prescription Insurance Information (Please Fax a Copy of Insurance Card)

Primary Pharmacy Insurance:

*Prescription Coverage Plan Name: _____

Beneficiary/Cardholder: _____ Relationship to Cardholder: _____

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

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

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

Secondary Pharmacy Insurance:

Secondary Prescription Coverage Plan Name: _____

Beneficiary/Cardholder: _____ Relationship to Cardholder: _____

Secondary Insurance ID #: _____ Secondary Group #: _____

Secondary BIN: _____ Secondary PCN: _____ Secondary Phone: _____

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

Patient Does Not Have Insurance ☐

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Questions?
Phone: **833-LIGHT-00 (833-544-4800)**

PATIENT AUTHORIZATION

Authorization for Use and Disclosure of My Health Information

I authorize my health care providers, including the pharmacies I use and my health plan(s), to disclose to Insmed (the manufacturer of my prescription) and its affiliates, agents, contractors, and any other person or entity assisting Insmed in the administration of the *inLighten Patient Support* program, my personal information (e.g., my name, gender, date of birth, address) and information about my health, including the information provided by my health care provider on any Patient Enrollment Form (collectively, "My Health Information"), for the following purposes (collectively, the "Patient Support Program Purposes"):

- To facilitate my participation in the *inLighten Patient Support* program;
- To investigate, verify, and determine my insurance coverage;
- To provide financial assistance and support to facilitate access to my medications as prescribed by my health care provider;
- If applicable, to facilitate a voluntary training session educating on device use and successful treatment initiation;
- To determine my initial and continuing eligibility for other assistance programs;
- To use My Health Information to contact me by phone, mail, e-mail, or text message to request further information, discuss the enrollment process, send me educational materials related to and administer my participation in the *inLighten Patient Support* program, evaluate treatment progress and/or the effectiveness of the *inLighten Patient Support* program;
- For Insmed's internal business purposes of continuous improvement, including ongoing quality control, data analysis, product development, marketing, and research. This may include the use or development of automated tools and processes, such as those related to artificial intelligence; and
- To help ensure the accuracy and completeness of any forms, applications, or other documentation provided to Insmed by me or on my behalf

I understand that my pharmacy provider may receive financial remuneration from Insmed in exchange for My Health Information and/or for any therapy support services provided to me. I also understand that once My Health Information has been disclosed under this Authorization, federal privacy laws may no longer protect it and My Health Information may be subject to further disclosure. I further understand that if I decline to sign this Authorization, that will not affect my eligibility for health plan benefits or treatment by my health care providers, but I will not be able to participate in the *inLighten Patient Support* program. I understand I have the right to revoke this Authorization for any and all purposes at any time by notifying my health care provider in writing.

If I revoke this Authorization, I understand that my health care provider will stop making disclosures of My Health Information to the *inLighten Patient Support* program. However, I also understand that the uses and disclosures of My Health Information previously made by my health care provider to the *inLighten Patient Support* program in reliance on this Authorization will not be deemed invalid. This Authorization expires ten (10) years from the date of my signature, unless I revoke it or the expiration date is specified or mandated to be shorter by applicable state law. I understand that I am entitled to a copy of this Authorization once signed.

Patient Support Program Enrollment and Data Collection Consent

I agree to enroll in the *inLighten Patient Support* program provided by Insmed and verify that the information in the "Patient Information" section of this form is accurate and complete. I also agree that Insmed and its data processors, affiliates, agents, contractors, and any other person or entity assisting Insmed in the administration of the *inLighten Patient Support* program (which may include but not be limited to co-pay administrators, fulfillment/logistics partners, and patient educators) may collect, use, and disclose information about me, my finances, and my health, which may include my sensitive data and consumer health data, as listed below (collectively, "My Information"), for the Purposes defined in the Authorization for Use and Disclosure of My Health Information:

- Individual health conditions, treatment, diseases, or diagnosis;
- Social, psychological, behavioral, and medical interventions;
- Health-related surgeries or procedures;
- Use or purchase of prescribed medication;
- Bodily functions, vital signs, symptoms, or measurements related to health;
- Diagnoses or diagnostic testing, treatment, or medication;
- Data that identifies me as a consumer seeking health care services; and
- Health-related data that have been derived or inferred from the above.

I understand that I am not required to consent to processing of My Information for these purposes. However, I understand that if I do not consent, I will not be able to participate in the *inLighten Patient Support* program, as collection of My Information is necessary for Insmed to facilitate my participation. I understand I have the right to withdraw my consent to participate in the *inLighten Patient Support* program at any time. I also understand that, depending on where I live, applicable state law may grant me the right to request restrictions on Insmed's collection, use, and disclosure of My Information. If I withdraw my consent, I understand that the uses and disclosures of My Information previously made in reliance on this Consent will not be deemed invalid. To withdraw my consent to participate in the *inLighten Patient Support* program or to request restrictions on the collection, use, or disclosure of My Information, I understand that I may call 833-544-4800 or write to Insmed Incorporated, Attn: *inLighten Patient Support* program, 700 US Highway 202/206, Bridgewater, NJ 08807.

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