# Patient Support Services Enrollment Form for ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil)

ARISTADA® aripiprazole lauroxil CARE SUPPORT

# Cover Sheet

**This page is additional information and is not required for enrollment.**

**Fax completed forms to: 1-844-464-7171**

## EFFICIENT TIPS FOR ENROLLMENT:

- **If you attach a face sheet, please manually complete only the patient name and date of birth in Section 1**
- **Attach legible copies of insurance cards (front and back) instead of entering insurance information in Section 2**
- **Download and save the enrollment form with prescriber information populated in Section 5 to avoid completing this information each time**

## REMINDERS:

- **Both patient and prescriber signatures are required**
- **Original signatures are required**
- **All information on page 1 must be provided, unless otherwise noted**
- **Any missing information may require additional processing time**

## OPTIONAL SERVICES:

- **Patient Transition of Care Support, Patient Assistance Program, Co-pay Savings, and Alternate Patient Contact are all optional services that require a selection and additional patient signature at the bottom of page 3**

## STANDARD PATIENT SERVICES:

- **Benefit Verification**
- **Welcome Call***
- **Injection Reminder Calls from an ARISTADA Nurse Coordinator**

* Please indicate if Welcome Calls should occur before or after discharge if the patient is hospitalized.

**If you have questions or would like additional information, please call:**

**ARISTADA Care Support**

**1-866-ARISTADA (866-274-7823)**

Monday through Friday | 9 AM to 8 PM ET

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## 1 PATIENT INFORMATION

***A copy of the patient's face sheet can be used for this section once the name and birth date are entered.***

First Name: MI: Last Name:

Date of Birth: / / Last 4 Digits of SSN:

Gender: ☐ M ☐ F ☐

Address:

City: State: Zip Code:

Home Phone: ( ) - Cell Phone: ( ) -

Ok to leave message? ☐ Y ☐ N Patient's preferred language:

Email:

*Patient may list an alternate patient contact on page 3.*

## 2 PATIENT INSURANCE INFORMATION

***Attaching a legible copy of the front and back of the patient's insurance card(s) can be used instead of completing this section.***

Payment Method: ☐ Insured ☐ Self-pay ☐ Uninsured

(for Patient Assistance Program or Co-pay Savings, complete Section 10 and sign the Patient Authorization on pages 2 & 3)

**COMPLETE SECTION BELOW AND/OR ATTACH A COPY OF BOTH SIDES OF THE INSURANCE CARD(S), IF AVAILABLE**

### PRIMARY INSURANCE

Plan Name: Plan Phone: ( ) -

Policy #: Group #:

### SECONDARY INSURANCE *(if applicable)*

Plan Name: Plan Phone: ( ) -

Policy #: Group #:

### PHARMACY BENEFIT MANAGER (PBM)

PBM Name: PBM Phone: ( ) -

Policy #: Group #:

Rx Bin #: PCN #:

## 3 PATIENT DIAGNOSIS *(Check all that apply)*

**Primary Diagnosis Code:**

- ☐ F20.0 Paranoid schizophrenia
- ☐ F20.1 Disorganized schizophrenia
- ☐ F20.2 Catatonic schizophrenia
- ☐ F20.3 Undifferentiated schizophrenia
- ☐ F20.5 Residual schizophrenia
- ☐ F20.89 Latent schizophrenia/ other schizophrenia
- ☐ F20.9 Schizophrenia, unspecified

Patient has tried and failed the following medications:

Any known allergies?

☐ Check if patient has concurrent medication(s)

List Concurrent Medications:

## 4 PATIENT HOSPITALIZATION STATUS

Is the patient hospitalized: ☐ Yes ☐ No

What is the anticipated date of discharge? / /

Your patient will receive a Welcome Call from an ARISTADA Nurse Coordinator to set up injection reminder phone calls. Please select the best option for the date of Welcome Call: ☐ On the last day of hospitalization ☐ On the day after discharge

## 5 PRESCRIBER INFORMATION

Prescriber Name:

Tax ID #: NPI #:

State License #: PTAN:

Prescriber Phone: ( ) - Fax: ( ) -

Facility Name:

Address:

City: State: Zip Code:

Contact Name: Contact Phone: ( ) -

## 6 PRESCRIPTION INFORMATION

***(Prescriber signature must be the same as the prescriber name above); not required for patient transition support from hospital setting***

Patient Name: Date: / /

ARISTADA® ☐ 441 mg ☐ 662 mg ☐ 882 mg ☐ 1064 mg Qty: Refills:

ARISTADA INITIO® ☐ 675 mg Qty: 1 Refills: 0

Please check boxes for all products you wish to prescribe

Provider State License #: Directions:

By signing below, I verify that the information provided in this ARISTADA Care Support enrollment form is complete and accurate to the best of my knowledge. I understand that Alkermes, Inc. reserves the right at any time and for any reason, without notice, to modify this ARISTADA Care Support enrollment form or to modify or discontinue any services or assistance provided through ARISTADA Care Support. Finally, I authorize Alkermes, Inc. and its affiliates, representatives, and agents as my designated agents to use and disclose my patient's health information as necessary to verify the accuracy of any information provided; to provide any services requested through ARISTADA Care Support; to forward the above prescription, by fax or other mode of delivery, to a pharmacy for fulfillment; a health plan for authorization, an injection provider and (as applicable) to assess my patient's eligibility for financial assistance.

Sign Here **Prescriber's Signature (required)** ✕ _____

**(If applicable) Prescriber's Signature (No Stamps allowed)** _____

✕ _____ **Dispense as Written**

✕ _____ **Substitution Permitted**

**Date of Signature** / /

**PLEASE SEE IMPORTANT SAFETY INFORMATION ON PAGE 4. PLEASE SEE PRESCRIBING INFORMATION AND MEDICATION GUIDE FOR ARISTADA INITIO, PRESCRIBING INFORMATION AND MEDICATION GUIDE FOR ARISTADA, OR VISIT WWW.ARISTADA.COM. PLEASE REVIEW MEDICATION GUIDE WITH PATIENTS.**

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ARISTADA® aripiprazole lauroxil
CARE SUPPORT

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Phone: 1-866-ARISTADA (1-866-274-7823)

## 7 PATIENT AUTHORIZATION FOR USE/DISCLOSURE

By signing below, **I authorize: 1.** my prescribing healthcare provider, **2.** the healthcare provider who will administer ARISTADA INITIO® and/or ARISTADA® to me, **3.** the pharmacy(ies) to which my ARISTADA INITIO® and/or ARISTADA® prescription is sent for fulfillment (the "Pharmacy"), and **4.** my health plans and insurers (collectively, my "Healthcare Entities") to use and disclose to: **1.** Alkermes, Inc. and the companies working with Alkermes, Inc. to provide the ARISTADA INITIO® and/or ARISTADA® patient support services I request, which are McKesson, AllCare Plus Pharmacy, Inc. (collectively, "Alkermes") and **2.** my Contact(s), if designated in Section 10 (Optional Services) of this form, (together with Alkermes, the "Recipients") health information related to my medical condition, including information about my mental health condition(s), my treatment with ARISTADA INITIO® and/or ARISTADA®, my insurance coverage, as well as the information requested in this form (taken together, "Information") **for the specific purposes** of allowing Alkermes to facilitate: **1.** ordering, delivering and administering ARISTADA INITIO® and/or ARISTADA®, **2.** conducting reimbursement verification and obtaining payment from my health plan(s) and insurer(s), **3.** providing me with educational and therapy support services by mail, text-messaging, email and/or telephone, which may include sending me product information materials, treatment appointments and treatment reminders, **4.** referring me to, or determining my eligibility for, other programs, foundations or alternative sources of funding or coverage to help me with the costs of ARISTADA INITIO® and/or ARISTADA®. **Information May Be Further Disclosed:** I understand that Information disclosed pursuant to this authorization could be re-disclosed by a Recipient and may no longer be protected by federal privacy law.

I understand that signing this authorization is voluntary and if I do not sign this authorization it will not affect my ability to obtain treatment, insurance or insurance benefits from my Healthcare Entities. I understand, however, that if I do not sign this authorization, I will not be eligible to receive the educational, patient support or other services described in this form, which are being provided by, or on behalf of, Alkermes. I will consult with my healthcare provider before making any treatment decisions. I understand I have the right to receive a copy of this authorization after I sign. I understand that the Pharmacy may receive payment from Alkermes, Inc. in exchange for information.

I may withdraw this authorization at any time by mailing or faxing a written request to ARISTADA Care Support Program at 852 Winter Street, Waltham, MA 02451, fax number 1-844-464-7171. Withdrawal of this authorization will end my consent to further disclosures of Information authorized herein by my Healthcare Entities when they receive notice of my withdrawal, but will not affect previous disclosures and uses pursuant to this authorization or as permitted by applicable law. This authorization expires on the earlier of **(1)** five years from the date of signature below or **(2)** the maximum period permitted by applicable state law, unless I withdraw it earlier as set forth above.

Sign Here ✕ _____ **Patient Signature**

_____ **Date of Signature**

(  )  - _____ **Patient Phone**

**OR**

Sign Here ✕ _____ **Guardian/Legal Representative Signature‡**

_____ **Date of Signature**

_____ **Authority/Relationship to Patient**

‡ If patient does not have capacity to act alone under state law, signature of guardian or authorized legal representative is required.

## 8 PATIENT'S PREFERRED PHARMACY

☐ Check here if you would like ARISTADA Care Support to send the prescription to the pharmacy listed below.

Pharmacy Name: Pharmacy Phone: (  )  - Pharmacy Fax: (  )  -

Pharmacy Address: City: State: Zip Code:

## 9 PATIENT TRANSITION OF CARE SUPPORT (OPTIONAL)

ARISTADA Nurse Coordinators are available to help patients transition from one site of care to another. This includes shipment coordination, calling the new site of care, and calling the patient or alternate patient contact.

**Patient last received ARISTADA® on (date):** /  / **Patient's next ARISTADA injection is on (date):** /  /

Discharge Planner Name: Discharge Planner Phone: (  )  -

☐ Check here if you would like your patient to be transitioned to an office/facility where the patient will receive ARISTADA and/or follow-up. Complete the following if you know the office/facility where you would like them to be transferred.

Name of Provider or Facility: NPI #: Phone: (  )  - Staff Contact Name:

Address: City: State: Zip Code:

☐ Check here if you have not identified a follow-up provider for your patient to receive their next ARISTADA injection or their ongoing medication management.*

If you have requested injection services for your patient, ARISTADA Care Support will provide a selection of several injection providers, if available, based on geographic proximity to your patient's address listed on the enrollment form (from closest to farthest from such address).*

These options will be provided to you for your patient. We will also contact the selected injection services provider to help coordinate injection services.

*Healthcare provider enrollment and participation in the ARISTADA Provider Network is voluntary and free of charge and, along with provider-specific information in the ARISTADA Provider Network, is based solely on healthcare provider responses. Inclusion in the ARISTADA Provider Network does not imply a referral, recommendation, or endorsement by Alkermes, Inc. We recommend that you research the credentials, qualifications, and experience of each provider before confirming an appointment. Alkermes shall in no event be liable to you or to anyone for any decision made or action taken by you in the reliance on information in the ARISTADA Provider Network.

PLEASE SEE IMPORTANT SAFETY INFORMATION ON PAGE 4. PLEASE SEE PRESCRIBING INFORMATION AND MEDICATION GUIDE FOR ARISTADA INITIO, PRESCRIBING INFORMATION AND MEDICATION GUIDE FOR ARISTADA, OR VISIT WWW.ARISTADA.COM. PLEASE REVIEW MEDICATION GUIDE WITH PATIENTS.

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## 10 OPTIONAL SERVICES *(Complete applicable section(s) and sign below)*

### PATIENT ASSISTANCE PROGRAM *(Your application may be subject to audit or request for additional documentation.)*

☐ **Check here if you would like to be assessed for the Patient Assistance Program. I am a US Resident.** ☐ Yes ☐ No

### FINANCIAL INFORMATION *(All Values Should Reflect Yearly Amounts for Entire Household)*

**Total Gross Yearly Income:** _____

**Household Size:** _____

(Number of people who contribute to or are dependent on your household income.)

**Check the applicable box:**

☐ Attached is a copy of my most recent federal tax return

☐ I do not file federal taxes (Documentation from Prescriber may be required.)

☐ By completing this section, I understand that in order to qualify for the Alkermes Patient Assistance Program I must meet the program requirements. I certify that my household size and household income are accurate, as is my income documentation. I certify that the health insurance information or selection of "Uninsured" provided in Section 2 (page 1) is correct. I am not enrolled in, or covered by, any local, state, federal or other government program that pays for any portion of medication costs (including but not limited to Medicare or Medicaid, Medigap, VA, DOD, TRICARE or a residential correctional program). I understand that my eligibility will be based on additional program requirements and, if approved, I must reapply and continue to meet eligibility requirements on an ongoing basis as defined by the program in order to receive benefits. I certify that I will notify the Alkermes Patient Assistance Program at 1-866-274-7823 if my income or health insurance status changes in order to reassess my eligibility. I understand that if I am no longer eligible I will be removed from the program.

### CO-PAY SAVINGS

Eligible patients and their caregivers can complete the section below or download a co-pay card directly at **www.aristada.com/copay-savings**.

☐ By checking this box, I certify that:
I am 18 years or older, or am the legal guardian of a patient who is 18 years or older, being treated consistent with FDA-approved labeling, and understand the program rules, regulations, and terms and conditions. I am not enrolled in, or covered by, any local, state, federal or other government program that pays for any portion of medication costs, including but not limited to Medicare, including Medicare Part D or Medicare Advantage plans; Medicaid, including Medicaid Managed Care and Alternative Benefit Plans under the Affordable Care Act; Medigap; VA; DOD; TRICARE; or a residential correctional program.

☐ I agree that if my insurance changes, I will promptly notify ARISTADA Care Support at 1-866-274-7823 in order to confirm my continued eligibility.

### ALTERNATE PATIENT CONTACT

☐ **Check here if you would like to designate an alternate patient contact.**

☐ By completing this section, I authorize my Contact, listed below, to receive administrative information related to my treatment, such as appointment reminders, and to make decisions on my behalf—for which I will remain liable—regarding delivery of ARISTADA INITIO® and/or ARISTADA®. Alkermes is not liable for any decision(s) made by the Contact or actions taken in reliance on such Contact's decisions.

Contact Name: _____ Phone: (  ) - _____ Relationship to Patient: _____

By signing below, I request the optional patient services selected above and I agree to comply with all applicable program terms.

Sign Here ✖ _____ / / _____ ( ) - _____

**Patient Signature** **Date of Signature** **Patient Phone**

**OR**

Sign Here ✖ _____ / / _____ _____

**Guardian/Legal Representative Signature‡** **Date of Signature** **Authority/Relationship to Patient**

‡ If patient does not have capacity to act alone under state law, signature of guardian or authorized legal representative is required.

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ARISTADA® aripiprazole lauroxil CARE SUPPORT

## INDICATION and IMPORTANT SAFETY INFORMATION for ARISTADA INITIO® (aripiprazole lauroxil) and ARISTADA® (aripiprazole lauroxil) extended-release injectable suspension, for intramuscular use

### INDICATION

ARISTADA INITIO, in combination with oral aripiprazole, is indicated for the initiation of ARISTADA when used for the treatment of schizophrenia in adults.

ARISTADA is indicated for the treatment of schizophrenia in adults.

### IMPORTANT SAFETY INFORMATION

**WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS**

**Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ARISTADA INITIO and ARISTADA are not approved for the treatment of patients with dementia-related psychosis.**

**Contraindication:** Known hypersensitivity reaction to aripiprazole. Reactions have ranged from pruritus/urticaria to anaphylaxis.

**Cerebrovascular Adverse Reactions, Including Stroke:** Increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack), including fatalities, have been reported in placebo-controlled trials of elderly patients with dementia-related psychosis treated with risperidone, aripiprazole, and olanzapine. ARISTADA INITIO and ARISTADA are not approved for the treatment of patients with dementia-related psychosis.

**Potential for Dosing and Medication Errors:** Medication errors, including substitution and dispensing errors, between ARISTADA INITIO and ARISTADA could occur. ARISTADA INITIO is intended for single administration in contrast to ARISTADA which is administered monthly, every 6 weeks, or every 8 weeks. Do not substitute ARISTADA INITIO for ARISTADA because of differing pharmacokinetic profiles.

**Neuroleptic Malignant Syndrome (NMS):** A potentially fatal symptom complex may occur with administration of antipsychotic drugs, including ARISTADA INITIO and ARISTADA. Clinical manifestations of NMS include hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available.

**Tardive Dyskinesia (TD):** The risk of developing TD (a syndrome of abnormal, involuntary movements) and the potential for it to become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic increase. The syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. Prescribing antipsychotics should be consistent with the need to minimize TD.

Discontinue ARISTADA if clinically appropriate. TD may remit, partially or completely, if antipsychotic treatment is withdrawn.

**Metabolic Changes:** Atypical antipsychotic drugs have been associated with metabolic changes that include:

- **Hyperglycemia/Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis, coma, or death, has been reported in patients treated with atypical antipsychotics. There have been reports of hyperglycemia in patients treated with oral aripiprazole. Patients with diabetes should be regularly monitored for worsening of glucose control; those with risk factors for diabetes should undergo baseline and periodic fasting blood glucose testing. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia, including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients require continuation of antidiabetic treatment despite discontinuation of the suspect drug.
- **Dyslipidemia:** Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.
- **Weight Gain:** Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

**Pathological Gambling and Other Compulsive Behaviors:** Compulsive or uncontrollable urges to gamble have been reported with use of aripiprazole. Other compulsive urges less frequently reported include sexual urges, shopping, binge eating and other impulsive or compulsive behaviors which may result in harm for the patient and others if not recognized. Closely monitor patients and consider dose reduction or stopping aripiprazole if a patient develops such urges.

**Orthostatic Hypotension:** Aripiprazole may cause orthostatic hypotension which can be associated with dizziness, lightheadedness, and tachycardia. Monitor heart rate and blood pressure, and warn patients with known cardiovascular or cerebrovascular disease and risk of dehydration and syncope.

**Falls:** Antipsychotics including ARISTADA INITIO and ARISTADA may cause somnolence, postural hypotension or motor and sensory instability which may lead to falls and subsequent injury. Upon initiating treatment and recurrently, complete fall risk assessments as appropriate.

**Leukopenia, Neutropenia, and Agranulocytosis:** Leukopenia, neutropenia and agranulocytosis have been reported with antipsychotics. Monitor complete blood count in patients with pre-existing low white blood cell count (WBC)/absolute neutrophil count or history of drug-induced leukopenia/neutropenia. Discontinue ARISTADA INITIO and/or ARISTADA at the first sign of a clinically significant decline in WBC and in severely neutropenic patients.

**Seizures:** Use with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

**Potential for Cognitive and Motor Impairment:** ARISTADA INITIO and ARISTADA may impair judgment, thinking, or motor skills. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are certain therapy with ARISTADA INITIO and/or ARISTADA does not affect them adversely.

**Body Temperature Regulation:** Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Advise patients regarding appropriate care in avoiding overheating and dehydration. Appropriate care is advised for patients who may exercise strenuously, may be exposed to extreme heat, receive concomitant medication with anticholinergic activity, or are subject to dehydration.

**Dysphagia:** Esophageal dysmotility and aspiration have been associated with antipsychotic drug use; use caution in patients at risk for aspiration pneumonia.

**Concomitant Medication:** ARISTADA INITIO is only available at a single strength as a single-dose pre-filled syringe, so dosage adjustments are not possible. Avoid use in patients who are known CYP2D6 poor metabolizers or taking strong CYP3A4 inhibitors, strong CYP2D6 inhibitors, or strong CYP3A4 inducers, antihypertensive drugs or benzodiazepines.

Depending on the ARISTADA dose, adjustments may be recommended if patients are 1) known as CYP2D6 poor metabolizers and/or 2) taking strong CYP3A4 inhibitors, strong CYP2D6 inhibitors, or strong CYP3A4 inducers for greater than 2 weeks. Avoid use of ARISTADA 662 mg, 882 mg, or 1064 mg for patients taking both strong CYP3A4 inhibitors and strong CYP2D6 inhibitors. (See Table 4 in the ARISTADA full Prescribing Information.)

**Commonly Observed Adverse Reaction:** In pharmacokinetic studies the safety profile of ARISTADA INITIO was generally consistent with that observed for ARISTADA. The most common adverse reaction (≥5% incidence and at least twice the rate of placebo reported by patients treated with ARISTADA 441 mg and 882 mg monthly) was akathisia.

**Injection-Site Reactions:** In pharmacokinetic studies evaluating ARISTADA INITIO, the incidences of injection-site reactions with ARISTADA INITIO were similar to the incidence observed with ARISTADA. Injection-site reactions were reported by 4%, 5%, and 2% of patients treated with 441 mg ARISTADA (monthly), 882 mg ARISTADA (monthly), and placebo, respectively. Most of these were injection-site pain and associated with the first injection and decreased with each subsequent injection. Other injection-site reactions (induration, swelling, and redness) occurred at less than 1%.

**Dystonia:** Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first days of treatment and at low doses.

**Pregnancy/Nursing:** May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure. Advise patients to notify their healthcare provider of a known or suspected pregnancy. Inform patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ARISTADA INITIO and/or ARISTADA during pregnancy. Aripiprazole is present in human breast milk. The benefits of breastfeeding should be considered along with the mother's clinical need for ARISTADA INITIO and/or ARISTADA and any potential adverse effects on the infant from ARISTADA INITIO and/or ARISTADA or from the underlying maternal condition.

**Please see full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.**

**PLEASE SEE PRESCRIBING INFORMATION AND MEDICATION GUIDE FOR ARISTADA INITIO, PRESCRIBING INFORMATION AND MEDICATION GUIDE FOR ARISTADA, OR VISIT WWW.ARISTADA.COM. PLEASE REVIEW MEDICATION GUIDE WITH PATIENTS.**

Alkermes®



ARISTADA® aripiprazole lauroxil CARE SUPPORT