# Patient Enrollment Form

ARISTADA CARE SUPPORT

ARISTADA INITIO® aripiprazole lauroxil extended-release injectable suspension 675 mg

ARISTADA® aripiprazole lauroxil extended-release injectable suspension 441 mg 662 mg 882 mg 1064 mg

**COMPLETE ALL FIELDS TO AVOID PROCESSING DELAYS.**
**PRESCRIPTION ONLY VALID IF FAXED.**
**FAX COMPLETED FORM TO: 1-844-464-7171.**
**QUESTIONS? CALL 1-866-ARISTADA (1-866-274-7823), 9AM–8PM (ET).**

**Prescriber Signature(s) (page 1) and Patient Signature(s) (pages 2-4) required. Patient Assistance Program Requirements on page 2.**

## 1. PLEASE SELECT PROGRAM OFFERING THAT BEST MEETS YOUR PATIENT'S NEEDS

- ☐ Benefits Verification
- ☐ Patient Assistance Program
- ☐ Co-pay Savings Program

## 2. PRESCRIBER OR FACILITY INFORMATION

Prescriber
(First) (Last)

Tax ID # State License #

NPI # PTAN #

Facility Name

Facility Phone # Fax #

Address

City State ZIP Code

Staff Name Staff Phone #

Staff Email Address

Additional Information

## 3. PATIENT INFORMATION

Name
(First) (Middle Initial) (Last)

Date of Birth Gender ☐ Male ☐ Female ☐ _____

Address

City State ZIP Code

Mobile Phone # Home Phone #

Phone Instructions (Best Number)

Email Address

→ *INSTRUCT PATIENT TO LIST ALTERNATE CONTACTS ON PAGE 3.*

## 4. PATIENT DIAGNOSIS

**Primary Diagnosis Code:**

**Possible Codes:**

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

**Patient has tried and failed the following medications**

**Any known allergies?**

**List concurrent medications**

## 5. PATIENT INSURANCE INFORMATION

A. Payment Method ☐ Insured ☐ Paying out-of-pocket

B. ATTACH COPY OF PATIENT'S (1) MEDICAL, (2) PHARMACY, *AND* (3) SECONDARY INSURANCE CARDS AS APPLICABLE (BOTH SIDES)

C. IF YOU DO NOT ATTACH INSURANCE CARD, COMPLETE SECTION BELOW.

Insurance Type ☐ Commercial ☐ Medicaid ☐ Medicare ☐ Other

Insurance Name

Policyholder Name PA # (if obtained)

Relationship to Patient Insurance Phone #

Policyholder Employer Name

Policy # Group ID #

Policy Type ☐ HMO ☐ PPO ☐ Other _____

PHARMACY BENEFIT PLAN (PBM)
PBM Name PBM Phone #

Member Name Member #

Relationship to Patient

Member Employer Name

Rx Group # Rx BIN # Rx PCN #

## 6. PRESCRIPTION INFORMATION

Patient Name _____
(Required – Please print full name)

Provider State License # Qty: 1 Refills: ___

☐ Inject IM ARISTADA 441mg monthly ☐ Inject IM ARISTADA 662mg monthly
☐ Inject IM ARISTADA 882mg monthly ☐ Inject IM ARISTADA 882mg every 6 weeks
☐ Inject IM ARISTADA 1064mg every 2 months

☐ Inject IM ARISTADA INITIO 675mg once as directed Qty: 1 Refills: 0

(Complete refills to minimize interruption in ARISTADA therapy)

By signing below, I certify that the therapy above is medically necessary. I authorize Alkermes, its affiliates, representatives and agents as my designated agents to forward the prescription, by fax or other mode of delivery, to a pharmacy for fulfillment.

Dispense as Written _____ Date _____
Prescriber Signature†
OR
Substitution Permitted _____ Date _____
Prescriber Signature†

†Prescriber Signature must be the same as the Prescriber Name. No stamps allowed.

Preferred Pharmacy Name

Phone # Fax #

☐ If Benefit Verification results specify a pharmacy other than preferred pharmacy, check here to allow triage to the pharmacy identified in Benefit Verification

☐ Pharmacist may inject

## 7. PRESCRIBER ATTESTATION

By signing below, I certify that (1) I have prescribed ARISTADA INITIO and/or ARISTADA based on my professional judgement of medical necessity and that I or others in my healthcare provider group ("my Practice") will supervise the patient's medical treatment; (2) I or others in my Practice have obtained the patient's authorization to the extent required by HIPAA or other applicable privacy laws (a) to disclose the patient information in this form to Alkermes, its agents and service providers ("Alkermes") and (b) for Alkermes to use and disclose the information to contact the patient and to provide reimbursement support services; and (3) the information is accurate to the best of my knowledge. I authorize Alkermes to act on my behalf for the limited purpose of transmitting the prescription(s) above and providing the patient information on this form to the appropriate dispensing pharmacy to the extent permitted under applicable law. I understand the information I provide about me may be used by Alkermes to provide me with information about the ARISTADA Care Support Program and Alkermes products and for analytical activities.

**Prescriber Signature** X _____ Date _____

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**PATIENTS SHOULD COMPLETE ALL FIELDS ON THIS PAGE.**

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## 8. PATIENT ASSISTANCE PROGRAM (PAP)

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

**FINANCIAL INFORMATION (ALL VALUES SHOULD REFLECT YEARLY AMOUNTS FOR ENTIRE HOUSEHOLD)**

**Total Gross Yearly Income:** _____

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

**Household Size:** _____

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

☐ **I do not file federal taxes** (Additional follow up or documentation may be required for patients who do not file taxes.)

☐ I understand that to qualify for PAP, my household income and household size must meet program requirements. I certify that my household size and household income, provided above, are accurate, as is my income documentation. I understand that my eligibility will be based on additional program requirements and, if approved, I must continue to meet eligibility requirements on an ongoing basis as defined by the program in order to receive benefits. Subject to continuing eligibility, patients will be approved for 6 months. Patients requiring assistance beyond 6 months will be required to reapply for continued program eligibility. I certify that I will notify ACS 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.

☐ 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 Alkermes, Inc. and the vendors associated with the PAP may obtain information about my credit profile from credit reporting agencies or other sources. I authorize this credit report to determine my PAP eligibility, and I acknowledge that this authorization extends to consumer reporting agencies and to subsequent reports in connection with PAP.

Your application may be subject to audit or request for additional documentation.

**Patient's Signature X** _____ **Date** _____ **Phone #** _____

**OR Guardian/Legal Representative Signature[‡] X** _____ **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.

## 9. CO-PAY SAVINGS PROGRAM INFORMATION FOR ELIGIBLE PATIENTS – COMPLETE SECTION IF YOU WOULD LIKE ACS TO SEND PRESCRIPTION TO PHARMACY WITH COPAY CARD INFORMATION.

**By signing below, I certify that:** I am at least 18 years old, or am the legal guardian of a patient who is 18 years old.

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 and Medicare Advantage plans
- Medicaid, including Medicaid Managed Care and Alternative Benefit Plans ("ABPs") under the Affordable Care Act
- Medigap
- Department of Defense ("DoD")
- TRICARE
- Veterans Administration ("VA")
- Residential Correctional Program

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

I have reviewed and agree to comply with the Co-pay Savings Program Terms and Conditions, including the eligibility requirements described above. For Complete ARISTADA Co-pay Savings Program Terms and Conditions, visit https://www.aristada.com/copay-savings.

**Patient's Signature X** **Print Name** **Date**

**OR Guardian/Legal Representative Signature[‡] X** **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.

## 10. DESIGNATED PATIENT CONTACT(S)

**By signing below, I designate my Contact(s), listed below, as my personal representatives ("Designated Contact(s)") with respect to my treatment with ARISTADA and/or ARISTADA INITIO (the "Product(s)"), including to receive information related to my treatment with the Product(s), and make decisions on my behalf regarding delivery of the Product(s). I authorize Alkermes and my Healthcare Providers to communicate with my Designated Contact(s) to coordinate the delivery, receipt, or storage of the Product(s) for the purpose of administration of my medication at my next scheduled appointment as applicable.**

**Please list any Designated Contact(s) authorized as set forth above:**

| Designee Name (1) | Relationship | Phone # | Email |
|---|---|---|---|
| **Designee Name (2)** | **Relationship** | **Phone #** | **Email** |

**Patient's Signature X** **Print Name** **Date**

**OR Guardian/Legal Representative Signature[‡] X** **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.

## 11. PATIENT AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION (REQUIRED)

By signing below, I authorize my "Healthcare Providers" (e.g., my physicians, pharmacists, pharmacies, other healthcare providers, and their staff) and my "Insurers" (e.g., my health insurance plan listed in Section 5) to share information about me as detailed in this Enrollment Form (my "Personal Information"). My "Personal Information" includes any and all information related to my health, including my diagnosis and treatment. My Personal Information also includes my or my Designated Contact's (see Section 10) identifying information, contact information, my health insurance information, financial information relevant to my eligibility for ARISTADA Care Support Program services, and all other information described on this Enrollment Form.

I authorize my Healthcare Providers and Insurers to share my Personal Information with Alkermes, Inc., its affiliated companies, agents, and service providers for the Aristada Care Support Program (collectively, "Alkermes") so they may provide the services described below (the "Services").

I authorize Alkermes to use and share my Personal Information with my Healthcare Providers, Insurers, and Designated Contact(s) to perform the Services, including: 1. ordering, delivering and administering ARISTADA INITIO and/or ARISTADA (the "Product(s)"); 2. conducting reimbursement verification and obtaining payment from my Insurer; 3. providing me with educational and therapy support services by using my provided contact information to communicate with me by mail, text message, e-mail, and/or telephone, which may include treatment reminders, information about the ARISTADA Care Support Program or the ARISTADA Co-pay Savings Program, and motivational messages; 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 the Product(s); 5. helping with my enrollment and continued participation in the ARISTADA Co-pay Savings Program in the event I am eligible for such program; and 6. conducting analysis to help Alkermes evaluate, create, and improve products and services for patients prescribed Alkermes medications.

I understand that once Personal Information is disclosed pursuant to this authorization, some of the information may not be regulated by applicable privacy regulations and could be re-disclosed, but I also understand that Alkermes does not intend to make any disclosures other than as described in this authorization. I understand that my pharmacy may receive remuneration in exchange for the use or disclosure of my Personal Information and/or any patient support services provided to me.

## 11. PATIENT AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION, CONTINUED (REQUIRED)

I understand I have the right to receive a copy of this authorization after I sign. I understand that signing this authorization is voluntary, and that if I do not sign this consent, it will not affect my ability to obtain treatment, insurance or insurance benefits. I understand, however, that if I do not sign this consent, I will not be eligible to receive the financial, educational, or other services provided by the ARISTADA Care Support Program.

I may withdraw this authorization at any time by mailing or faxing a written request to ARISTADA Care Support, 900 Winter Street, Waltham, MA 02451, 1-800-948-7628. Withdrawal of this authorization will not, however, invalidate disclosures and uses of my Personal Information prior to the date my notice of withdrawal is received by Alkermes.

This consent expires five (5) years from the date of my signature below unless an earlier expiration is mandatory under applicable state law.

For additional information about our privacy practices, please visit https://www.Alkermes.com/privacy-policy.

| Patient's Signature X | Print Name | Date |
|---|---|---|
| OR Guardian/Legal Representative Signature[‡] X | | 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.

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

ARISTADA® CARE SUPPORT

ARISTADA INITIO® aripiprazole lauroxil extended-release injectable suspension 675 mg

ARISTADA® aripiprazole lauroxil extended-release injectable suspension 441 mg 662 mg 882 mg 1064 mg

## 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 Reactions:** 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.

**To report SUSPECTED ADVERSE REACTIONS, contact Alkermes at 1-888-238-8008 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

**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 ARISTADA.COM. PLEASE REVIEW MEDICATION GUIDE WITH PATIENTS.**

Alkermes®