ARISTADA® Provider Network Agreement

ARISTADA aripiprazole lauroxil CARE SUPPORT

This agreement pertains to ARISTADA INITIO™ (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil). 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. Please see the following pages for additional Important Safety Information and see **full Prescribing Information ARISTADA INITIO, and full Prescribing Information ARISTADA** including Boxed Warning for ARISTADA INITIO and ARISTADA.

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.

Terms of Participation

The name, address and other information that you provide to Alkermes, Inc. will be used by Alkermes, Inc. and entities that work with Alkermes Inc. to provide ARISTADA INITIO™ and/or ARISTADA® patient services pursuant to which your information may be made available, through a call center, website listing or other means, to other healthcare providers, patients, caregivers and consumers who wish to access healthcare service from you as an ARISTADA INITIO™ and/or ARISTADA® Injection Provider and/or as an ARISTADA INITIO™ and/or ARISTADA® Medical Management Provider providing ARISTADA INITIO™ and/or ARISTADA® treatment to appropriate patients.

In order to be included in the ARISTADA Provider Network, and identified as an ARISTADA INITIO™ and/or ARISTADA® Injection Provider and/or Medical Management Provider the healthcare provider must be validly licensed (as required by state or federal law) and meet all of the following criteria:

A. Familiar with the Prescribing Information for ARISTADA INITIO™ and ARISTADA®
B. Accepting referrals, of patients living with schizophrenia, for the purpose of administering an intramuscular injection of ARISTADA INITIO™ and ARISTADA® , provided such patients meet the requirements of the healthcare provider's practice; C. Familiar with the proper preparation and administration of ARISTADA INITIO™ and ARISTADA® as set forth in the ARISTADA INITIO™ and ARISTADA® Prescribing Information, and
D. Able to administer ARISTADA INITIO™ and ARISTADA® in a private room or private area within your site of care

In order to be included within the ARISTADA Provider Network and identified as an ARISTADA INITIO™ and/or ARISTADA® Medical Management Provider, the healthcare provider must be validly licensed (as required by state or federal law) and meet all of the following criteria:

E. Familiar with the Prescribing Information for ARISTADA INITIO™ and/or ARISTADA® and
F. Accepting referrals of patients living with schizophrenia for the purpose of clinical assessment of treatment with ARISTADA INITIO™ and/or ARISTADA® and prescribing of ARISTADA INITIO™ and/or ARISTADA® treatment to appropriate patients, provided such patients meet the requirements of the healthcare provider's practice;

Inclusion in the ARISTADA Provider Network does not represent, and is not to be used in any manner as, an endorsement, referral or recommendation by Alkermes. This agreement shall not be used or construed as an inducement to, or reward for, the referral of patients or the use of any Alkermes' product.

The administering healthcare provider is solely responsible for the quality of all healthcare provided.

The undersigned acknowledges that he/she has received, read and understands the full Prescribing Information for ARISTADA INITIO™ and/or ARISTADA® and that he/she meets the applicable healthcare provider requirements stated above and requests inclusion as an ARISTADA INITIO™ and/or ARISTADA® injection Provider and/or ARISTADA INITIO™ and/or ARISTADA® Medical Management Provider as designated below.

Please see additional Important Safety Information provided on Page 4.

Please see the full Prescribing Information, including Boxed Warning and Medication Guide at www.ARISTADA.com or call 1-866-ARISTADA.

ARISTADA® Provider Network Agreement

ARISTADA aripiprazole lauroxil CARE SUPPORT

Please fax completed agreement to: 781-207-8588

PRIMARY FACILITY:
Check all Services that the Provider is offering at this Facility:
☐Injections ☐ Medical Management

TYPE OF FACILITY:

☐ Private Practice	☐ Group Practice	☐Pharmacy	☐ Pharmacy Traveling Nurse Network	☐ Visiting Nurse Association (VNA)
☐ Mobile Van	☐ Behavioral Health Center	☐ Injection Clinic	☐ Clinic	☐ Community Mental Health Center (CMHC)
☐ Treatment Center	☐ Inpatient Hospital	☐ Psychiatric Hospital	☐ Other (specify):	

Legal Name of Primary Practice/Facility _____Phone_____
Fax_____Address_____City_____
State _____Zip _____Facility Website_____DEA #_____
NPI #_____Email _____Best Time to Call _____

Will this organization have multiple sites available for services under this Agreement? ☐Yes ☐ No
If yes, please list all additional locations on Page 3.

PRIMARY PROVIDER:
Name of primary provider for service at the above facility: _____
Does the primary provider at this facility also have a secondary facility? ☐Yes ☐No (If yes, please complete Page 3. of this form.) Are there secondary providers at the above facility or at an affiliated facility? ☐Yes ☐ No (If yes, please complete Page 3. of this form.)

By signing the below, I hereby certify that I have read, understood and agree to comply with the terms of participation set forth above. If at any time Alkermes determines the applicable healthcare provider criteria are not met, Alkermes may remove my name and related facilities from this program. The undersigned is the above-named provider, or if I am signing on behalf of a facility, I certify that I am authorized to do so.

Name/Title (please print) _____

Signature _____Date of Signature _____

Alkermes reserves the right to alter or discontinue this program at its discretion. If you wish to remove your organization, practice or any of your sites from this program please notify ARISTADA Care Support at 866-274-7823.

Additional Provider Sites
Please list all additional provider sites. If preferred, you may attach a spreadsheet with the following fields provided for each location. You agree that this additional information may be provided upon request for an ARISTADA INITIO™ and/or ARISTADA® Provider.

If this request is for a Pharmacy traveling nurse network/visiting nurse association, please attach a document to this fax that indicates all servicing zip codes and/or counties.

Please see additional Important Safety Information provided on Page 4.

Please see the full Prescribing Information, including Boxed Warning and Medication Guide at www.ARISTADA.com or call 1-866-ARISTADA.

ARISTADA aripiprazole lauroxil CARE SUPPORT

ADDITIONAL PROVIDER AND FACILITY INFORMATION:

ADDITIONAL FACILITY:
Check all Services that the Provider is offering at this Facility:
☐Injections ☐ Medical Management

TYPE OF FACILITY:

☐ Private Practice	☐ Group Practice	☐Pharmacy	☐ Pharmacy Traveling Nurse Network	☐ Visiting Nurse Association (VNA)
☐ Mobile Van	☐ Behavioral Health Center	☐ Injection Clinic	☐ Clinic	☐ Community Mental Health Center (CMHC)
☐ Treatment Center	☐ Inpatient Hospital	☐ Psychiatric Hospital	☐ Other (specify):	

Legal Name of Secondary Practice/Facility _____Phone_____
Fax_____Address_____City_____
State _____Zip _____Facility Website_____DEA #_____
NPI #_____Email _____Best Time to Call _____

ADDITIONAL PROVIDER AND FACILITY INFORMATION:

ADDITIONAL PROVIDER 1:
Name of secondary provider _____

Legal Facility name of secondary provider _____

By signing below, I hereby certify that I have read, understood and agree to comply with the terms of participation set forth above. The undersigned is the above-named provider, or if I am signing on behalf of a facility, I certify that I am authorized to do so.

Name/Title (please print) _____

Signature _____Date of Signature _____

ADDITIONAL PROVIDER 2:
Name of tertiary provider _____

Legal Facility name of tertiary provider _____

By signing below, I hereby certify that I have read, understood and agree to comply with the terms of participation set forth above. The undersigned is the above-named provider, or if I am signing on behalf of a facility, I certify that I am authorized to do so.

Name/Title **(please print)** _____

Signature _____Date of Signature_____

Please see additional Important Safety Information provided on Page 4.

Please see the full Prescribing Information, including Boxed Warning and Medication Guide at www.ARISTADA.com or call 1-866-ARISTADA.

ARISTADA® Provider Network Agreement

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.

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 only. 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 CYPD6 poor metabolizers or taking strong CYP3A4 inhibitors, strong CYPD6 inhibitors, or strong CYP3A4 inducers, antihypertensive drugs or benzodiazepines.

Depending on the ARISTADA dose, adjustments may be recommended if the patients are 1) known as CYP2D6 poor metabolizers and/or 2) taking CYP3A4 inhibitors, CYP2D6 inhibitors, or 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.

PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING FOR ARISTADA INITIO AND ARISTADA.

ARI-003171-V2 Printed in U.S.A.

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