ARISTADA® aripiprazole lauroxil Care Support

Cover Sheet

This page is provided as a guide and is not required for enrollment.

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

INSTRUCTIONS

- **Please ensure that prescriber and patient signatures are obtained.**
- **Attach a copy of both sides of the patient's insurance card(s).**
- **Face sheets will be accepted, but cannot replace the patient and provider signatures.**

List of application components needed to ensure that ARISTADA Care Support can provide assistance.

Page 1: (Required for Services unless otherwise noted)

- ☐ Complete **Section 1. Patient Information**
- ☐ Complete **Section 2. Patient Insurance Information**
- ☐ Provide **Section 3. Primary Diagnosis Code** for Benefits Verification and Patient Assistance Program
- ☐ Complete **Section 4. Prescriber Information**
- ☐ Provide **Section 4. Facility Contact Information** for follow-up questions
- ☐ Complete **Section 5. Prescription Information** (Not required for Patient Transition Support from an inpatient Hospital Setting)
- ☐ **Section 5. Provider Attestation**

Page 2:

- ☐ Provide **Section 7. Patient Transition of Care Support** (Optional Service)
- ☐ **Section 8. Patient Authorization** to use/disclose information (Patient Signature Required for All Services)

Page 3: (Optional Services and Other – Patient Signatures Required for Optional Services)

- ☐ Provide **Section 9. Patient Financial Information, including Income Documentation, and Household Size** (if applying for **Patient Assistance Program**)
- ☐ Complete **Section 9. Co-pay Assistance** (if applying)
- ☐ Complete **Section 9. Alternate Patient Contact** (optional)
- ☐ **Section 10. Marketing Communications** authorization (Patient Signature Required to Opt-in)

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

ARISTADA Care Support

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

Monday through Friday | 8 AM to 8 PM EST

Patient Support Services Enrollment Form for ARISTADA® (aripiprazole lauroxil)

ARISTADA® aripiprazole lauroxil Care Support

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1. PATIENT INFORMATION

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 alternate patient contact on page 3.

2. PATIENT INSURANCE INFORMATION

Payment Method: ☐ Insured ☐ Self-pay ☐ Uninsured
(for Patient Assistance Program or Co-Pay Assistance, complete Section 9 and sign authorization on page 3)

COMPLETE SECTION BELOW AND 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. PRESCRIBER INFORMATION

Prescriber Name:

Tax ID #: NPI #:

State License #: PTAN:

Prescriber Phone: ( ) - Fax: ( ) -

Facility Name:

Address:

City: State: Zip Code:

Contact Name: Contact Phone: ( ) -

5. 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:

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 The Lash Group, Inc. 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 / /

6. PATIENT 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:

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

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7. PATIENT TRANSITION OF CARE SUPPORT

ARISTADA Care Nurses 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):** / /

☐ Check here if you would like your patient to receive assistance transitioning to a new site of care.

Discharge Planner Name: Discharge Planner Phone: ( ) -

If your office/facility will **NOT** be injecting ARISTADA®, please provide the name of your patient's injection provider below.

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

Address: City: State: Zip Code:

☐ Check here if you have **NOT** identified an injection provider for your patient and your patient would like assistance locating one.†

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 Alkermes Provider Network is voluntary and free of charge and, along with provider-specific information in the Alkermes Provider Network, is based solely on healthcare provider responses. Inclusion in the Alkermes 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 Alkermes Provider Network.

8. PATIENT AUTHORIZATION FOR USE/DISCLOSURE

By signing below, **I authorize: 1.** my prescribing healthcare provider, **2.** the healthcare provider who will administer ARISTADA® to me, **3.** the pharmacy(ies) to which my 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® patient support services I request, which are McKesson, The Lash Group, Inc. (collectively, "Alkermes") and **2.** my Contact(s), if designated in Section 9 (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®, 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®, **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®. **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 PO Box 220549, Charlotte, NC 28222-0549, 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.

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9. 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 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 ASSISTANCE

☐ **Check here if you would like to receive co-payment assistance from Alkermes, Inc.**

☐ I certify that I am at least 18 years old, I am being treated for schizophrenia and that I am **NOT** eligible to use benefits from any federal, state or government funded program to help pay for my prescription. Such programs include, but are not limited to:

- Medicare, including Medicare Part D or Medicare Advantage plans
- Medicaid, including Medicaid Managed Care and Alternative Benefit Plans ("ABPs" under the Affordable Care Act)
- Medigap
- Veterans Administration ("VA")
- Department of Defense ("DoD")
- TRICARE®
- Any state funded programs such as medical or pharmaceutical assistance programs

If you become eligible for benefits from state, federal or government funded programs, such as those listed above, to help pay for your prescription for ARISTADA®, you will no longer be eligible to participate in this program.

☐ By completing this section, I understand that in order to qualify for co-payment assistance from Alkermes, Inc. that I must meet the requirements set forth. I certify that I am at least 18 years old, I am being treated for schizophrenia and that I am NOT eligible to use benefits from any federal, state or government funded program to help pay for my prescription. I certify that if I become eligible for benefits from state, federal or government funded programs, such as those listed above, to help pay for my prescription of ARISTADA®, that I will no longer be eligible to participate in this program. I certify that if my insurance changes, I agree to promptly notify ARISTADA Care Support at 1-866-274-7823 so that you can 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®. 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.

10. MARKETING COMMUNICATIONS BY ALKERMES *(optional)*

☐ **Caregiver** ☐ **Patient** | **I would like to sign up for marketing communications, including emails, from Alkermes**

Sign Here ✕ Signature: Email:

OR

Sign Here ✕ Guardian/Legal Representative Signature‡: Email:

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

INDICATION

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 is 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 is not approved for the treatmentof patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): A potentially fatal symptom complex sometimes referred to as NMS may occur with administration of antipsychotic drugs, including 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 should be consistent with the need to minimize TD. Discontinue ARISTADA if clinically appropriate. Tardive Dyskinesia 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 ARISTADA 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 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. Patients with a history of clinically significant low white blood cell count (WBC)/absolute neutrophil count (ANC) and history of drug-induced leukopenia/neutropenia should have frequent complete blood count (CBC) during the first few months of receiving ARISTADA. Consider discontinuation of ARISTADA at the first sign of a clinically significant decline in WBC count in the absence of other causative factors. Monitor patients with clinically significant neutropenia for fever or other symptoms or signs of infection and treat promptly if such symptoms or signs occur. Discontinue ARISTADA in patients with severe neutropenia (absolute neutrophil count $<1000/mm^3$) and follow their WBC until recovery.

Seizures: ARISTADA should be used with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

Potential for Cognitive and Motor Impairment: ARISTADA may impair judgment, thinking, or motor skills. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are certain 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: Decreasing the ARISTADA dosage is recommended in patients taking strong CYP3A4 inhibitors and/or strong CYP2D6 inhibitors for longer than 2 weeks. Increasing the ARISTADA dosage from 441 mg to 662 mg is recommended in patients taking CYP3A4 inducers for longer than 2 weeks. No ARISTADA dosage changes are recommended for patients taking CYP450 modulators for less than 2 weeks.

Most Commonly Observed Adverse Reaction: 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: 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 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 and any potential adverse effects on the infant from ARISTADA or from the underlying maternal condition.

PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

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