

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

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.

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



Prescription only valid if faxed
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Phone: 1-866-ARISTADA (1-866-274-7823)

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: _____

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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

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:

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



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 treatment of 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/mm³) 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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