A benefit verification was completed for your patient on <Date> by <Senior Case Manager>. Based on our research, ARISTADA® (aripiprazole lauroxil) is <covered/not covered>.

If you have any questions about this Summary of Benefits or ARISTADA®, please contact ARISTADA® Care Support at 1-866-ARISTADA (1-866-274-7823) Monday through Friday, 8am – 5pm, Eastern Time.

**SUMMARY OF BENEFITS FOR:**

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<td><strong>Drug Copay</strong>&lt;br&gt;<strong>Drug Coinsurance/Copay</strong>&lt;br&gt;<strong>Out-of-Pocket Maximum</strong>&lt;br&gt;<strong>Provider Preferred Pharmacy</strong>&lt;br&gt;<strong>Provider Standard Pharmacy</strong>&lt;br&gt;<strong>Prior Authorization Coverage and Criteria Requirements</strong>&lt;br&gt;<strong>PA Required?</strong>&lt;br&gt;<strong>VNM</strong>&lt;br&gt;<strong>Verbal PA Allowed?</strong>&lt;br&gt;<strong>VNM</strong>&lt;br&gt;<strong>PA Form</strong>&lt;br&gt;<strong>Other/Additional Documentation</strong></td>
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This is not a guarantee of payment, coverage or reimbursement. Alkermes does not provide any advice, recommendation, guarantee or warranty relating to coverage, reimbursement or costs for any product or service. Healthcare providers are responsible for determining coverage and reimbursement information and ensuring the accuracy and completeness of claim submissions for their patients. Coverage, reimbursement and costs vary significantly by payer, provider and setting of care and are subject to change. Additional information may exist. Actual coverage and reimbursement decisions are made by individual payers.

**INDICATION**

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

**IMPORTANT SAFETY INFORMATION 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.

For live support, call 1-866-ARISTADA (1-866-274-7823), Monday through Friday, 9 AM to 8 PM EST.
IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA

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 treatment of schizophrenia in adults. 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 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 phosphokinas, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential for 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 Dyskenisia (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.

**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 the patient 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 known CYP2D6 poor metabolizers and/or 2) taking strong CYP3A4 inhibitors, strong CYP2D6 inhibitors, or strong CYP3A4 inducers for greater than 2 weeks. Avoid use in patients taking 882 mg, 882 mg, or 1064 mg for patients taking both CYP2D6 poor metabolizers and/or 2) taking strong CYP3A4 inhibitors, strong CYP2D6 inhibitors, or strong CYP3A4 inducers for greater than 2 weeks. Avoid use in patients taking both CYP2D6 poor metabolizers and/or 2) taking strong CYP3A4 inhibitors, strong CYP2D6 inhibitors, or strong CYP3A4 inducers for greater than 2 weeks.

**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, 882 mg, and 882 mg ARISTADA (monthly), 882 mg ARISTADA (monthly), and placebo, respectively. Most of these were injection-site pain and reaction which were mild to moderate. No patient discontinued ARISTADA INITIO or ARISTADA due to injection-site reaction.

**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/ARISTADA during pregnancy. Aripiprazole is present in human milk. The benefits of breastfeeding should be considered along with the mother’s clinical need for ARISTADA INITIO and/or ARISTADA during breastfeeding. Aripiprazole can cross into breast milk. The benefits of breastfeeding should be considered along with the mother's clinical need for ARISTADA INITIO and/or ARISTADA during breastfeeding.

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