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.

**Contraindication:** Known hypersensitivity reaction to aripiprazole. Reactions have ranged from pruritus/urticaria to anaphylaxis.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
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Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
ARISTADA INITIO AND ARISTADA
IMPORTANT SAFETY INFORMATION

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
IMPORTANT SAFETY INFORMATION

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 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

Please see additional Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
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.

Please see additional **Important Safety Information** on pages 4-7 and full Prescribing Information, including Boxed Warning, for **ARISTADA INITIO** and **ARISTADA**.

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**IMPORTANT SAFETY INFORMATION (cont’d)**
IMPORTANT SAFETY INFORMATION (cont’d)

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.

Please see additional Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
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.

Please see full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
INTRODUCTION
INTRODUCTION

Guide Overview
The ARISTADA INITIO and ARISTADA Reimbursement Guide is designed to help support patient access to ARISTADA INITIO® (aripiprazole lauroxil) and ARISTADA® (aripiprazole lauroxil), and provides an overview of useful information for healthcare professionals to navigate key aspects of coding, coverage, and payment for treatment with ARISTADA INITIO and/or ARISTADA, on behalf of patients, in the following settings of care:

- Healthcare professional offices and community mental health centers (CMHCs)
- Hospital outpatient department (HOPD) and partial hospitalization treatment programs
- Hospital inpatient

Tips for Using This Guide
Page 14 of this guide provides a comprehensive look at the process to start treatment with ARISTADA INITIO and/or ARISTADA and action items for each step.

The reimbursement guide has been divided by site of care. Please see tabs to the right for site-specific information.

This guide outlines a general access process. For patient-specific coverage information, please contact ARISTADA Care Support at 1-866-ARISTADA (1-866-274-7823) Monday–Friday 9 AM to 8 PM ET.

Healthcare providers are responsible for keeping current and complying with all applicable coverage requirements and for the selection of diagnosis and procedure codes that accurately reflect their patient's condition and the services rendered. Healthcare providers are also responsible for the accuracy of all claims and related documentation submitted for reimbursement. Additional insurance requirements may apply, and healthcare providers should always contact the insurer directly to obtain complete and current information regarding coverage of ARISTADA INITIO and/or ARISTADA. Alkermes does not guarantee coverage or reimbursement. Under no circumstances will Alkermes, Inc., or its affiliates, employees, consultants, agents, or representatives be liable for costs, expenses, losses, claims, liabilities, or other damages that may arise from, or be incurred in connection with, the information provided here or any use thereof.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
ARISTADA CARE SUPPORT

ARISTADA Care Support offers a suite of services to make therapy more accessible for your patients. To connect with our support team, call 1-866-ARISTADA (1-866-274-7823), Monday–Friday, 9 AM to 8 PM ET.

Access Support

**Benefit investigation:** Once a patient is enrolled in ARISTADA Care Support, a benefit verification will be completed to determine the patient’s coverage and out-of-pocket costs for ARISTADA INITIO and/or ARISTADA.

**Prior authorization (PA) assistance:** If a PA is needed, ARISTADA Care Support will research requirements and communicate them back to you. A PA checklist is available in this guide or at [www.aristadacaresupport.com/all-resources-forms](http://www.aristadacaresupport.com/all-resources-forms).

**CoverMyMeds** offers free electronic PA services and the ability to:
- Find, complete, and submit PA requests for all plans
- Receive electronic determinations, often in real time
- Automatically renew previously submitted PA requests

CoverMyMeds is a third-party platform not owned by Alkermes.

**Claims appeal assistance:** If a claim is denied, ARISTADA Care Support can help obtain information regarding the denial of coverage and provide appeal requirements.

**Reimbursement and coding information:** In addition to the information provided in this guide, reimbursement and coding reference materials are available at [www.aristadacaresupport.com/reimbursement](http://www.aristadacaresupport.com/reimbursement). For patient-specific information, contact ARISTADA Care Support.

Please see **Important Safety Information** on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Assistance Programs

ARISTADA Co-pay Savings Program: Eligible, commercially insured patients may pay as low as a $10 co-pay per prescription for ARISTADA INITIO and/or ARISTADA. Restrictions apply.a

ARISTADA Patient Assistance Program: Eligible, uninsured or functionally uninsured patients may be provided ARISTADA INITIO and/or ARISTADA at no charge for up to 6 months. Restrictions apply.b

ARISTADA Clinical Educators
Contact ARISTADA Care support to schedule an appointment with clinical educators, who are registered nurses with experience in the mental health field.

ARISTADA Provider Network
The ARISTADA Provider Network provides access to those in search of a healthcare provider to administer ARISTADA to appropriate patients and/or provide medical management for patients with schizophrenia, including treatment with ARISTADA.

If you would like to access the online searchable database or if you are interested in joining the ARISTADA Provider Network, please visit www.aristadacaresupport.com/find-provider.

IMPORTANT: Healthcare provider enrollment and participation in the ARISTADA Provider Network is voluntary and free of charge and, along with the provider-specific information in the ARISTADA Provider Network, is based solely on healthcare provider responses. Inclusion in the ARISTADA Provider Network does not imply a referral, recommendation, or endorsement by Alkermes, Inc. Alkermes has no liability for any decision made or action taken in reliance on this information.

a Patients eligible to participate in this program must be 18 years or older, be treated consistent with the labeling approved by the Food and Drug Administration, have their medication covered by commercial insurance and not be 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 or Medicare Advantage plans; Medicaid, including Medicaid Managed Care and Alternative Benefit Plans under the Affordable Care Act; Medigap; Veterans Affairs; Department of Defense; TRICARE; or a residential correctional program. If patient becomes eligible for any government program that pays for any portion of medication costs, they will no longer be eligible for this program. Program may be subject to plan benefit design requirements. This offer is not conditioned on any past, present, or future purchase, including refills. Alkermes reserves the right to rescind, revoke, or amend this offer, program eligibility, and requirements at any time without notice. This offer is limited to one per patient; may not be used with any other offer; is not transferable; and may not be sold, purchased, or traded, or offered for sale, purchase, or trade. Void where prohibited by law. Program administrator or its designee will have the right upon reasonable prior written notice, during normal business hours, and subject to applicable law, to audit compliance with this program.

b The ARISTADA Patient Assistance Program does not cover or provide support for supplies, procedures, or any physician-related services associated with ARISTADA therapy. Patients must be uninsured or determined to be functionally uninsured, which means that despite having insurance, the patient is being denied coverage for the product. Patient must provide proof of household size and annual gross income and certify accuracy that they meet financial criteria. Prescription must be by a United States (US) licensed healthcare provider. Shipment must be delivered to a licensed healthcare provider at a location within the 50 states (excluding Puerto Rico and US territories). Patient must be prescribed ARISTADA INITIO and/or ARISTADA for an on-label use and be 18 years of age or older.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
OVERVIEW

ACCESSING ARISTADA INITIO AND ARISTADA

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

Introduction

Procurement and Ordering

Dosing and Administration

Coverage by Insurance Type

PAs, Exceptions, and Appeals

Coverages by Type

Overview ACCESS ARISTADA

Care Support ARISTADA

Information and Ordering

Hospital Inpatient Services

HOPD or CMHC

Provider Office

Administration and Ordering

Dosing and Administration
ACCESSING ARISTADA INITIO AND ARISTADA

ARISTADA is covered by 99% of healthcare plans including Medicare, Medicaid, and most commercial plans and is available on the Veterans Affairs and Indian Health Service national formularies.\(^3\)\(^-\)\(^5\)\(^a\)\(^b\) However, it is important to understand patient-specific coverage and reimbursement information.\(^a\)\(^b\)

1. **Complete a benefit verification to determine key information**
   - Is the product covered by the medical benefit or pharmacy benefit?
   - If the product is not covered, is there a formulary exception process?
   - Is a PA required?
   - Does the payer require that the product be dispensed by a specific pharmacy?
   - How does the payer classify your site of care?
   - What is the patient’s out-of-pocket cost?

To obtain patient-specific benefit information or co-pay assistance for eligible patients, contact ARISTADA Care Support at 1-866-ARISTADA (1-866-274-7823) or online at [www.aristadacaresupport.com](http://www.aristadacaresupport.com).

2. **Submit a PA or other utilization management information as needed**

For additional information on PAs or to access a PA checklist, please see page 24 in this guide.

CoverMyMeds is available for ARISTADA INITIO and/or ARISTADA.

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\(^a\) Data source: DRG Fingertip Formulary as of March 2022.
\(^b\) In accordance with VA criteria for use for long-acting injectables.

Please see **Important Safety Information** on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
3 Product acquisition

Buy and bill  Specialty pharmacy  Retail pharmacy

For information about product acquisition, please see page 31 in this guide.

4 Administration

Please visit www.aristadahcp.com/administration-instructions for instructions outlining proper administration of ARISTADA INITIO and/or ARISTADA.

5 Submit claim

Please refer to your specific site of care via the tabs to the right for coding information and a sample claim form.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
COVERAGE CONSIDERATIONS BY INSURANCE TYPE

There are 2 types of payers that provide coverage for people with schizophrenia: government programs funded by federal or state governments (eg, Medicare and Medicaid) and private (often known as commercial) insurance, which includes plans available to individuals through the health insurance marketplaces. Most health plans include mental health services as an essential health benefit and are required to be at parity with other medical and surgical services covered under the plan.

Figure 1. Insurance for People With Schizophrenia

**Medicaid**
- Low-income and other qualified populations
- Fee-for-service Medicaid
- Managed Medicaid

**Medicare**
- Aged ≥65 years or <65 years with certain disabilities
  - Part A—hospital insurance
  - Part B—medical insurance
  - Medicare Advantage (MA) or Medicare Advantage—Prescription Drug Plan (MA-PDP)
  - Part D—outpatient prescription drug plan

**Other Federal**
- Veterans Affairs, Department of Defense, TRICARE

**Employer**
- **Individual**, including marketplace

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Fee-for-Service Medicaid

Medicaid provides coverage for many people living with schizophrenia with fee-for-service (FFS); however, coverage and payment for prescription medications vary by state. Some programs or plans may have coverage restrictions on long-acting injectable antipsychotic medications such as quantity limits, PA, or step therapy. Other states may protect treatment for schizophrenia by considering it as a severe mental illness to ensure patients have access to care and treatment options, including treatment with drugs like ARISTADA INITIO and/or ARISTADA.

Managed Medicaid

Around 69% of Medicaid patients may receive coverage through a Managed Medicaid plan that is administered by a managed care organization. Patients who are enrolled in Managed Medicaid plans may have different coverage for ARISTADA INITIO and/or ARISTADA than patients covered under a state FFS Medicaid program. Some states carve out services from their managed care contracts; therefore, it is important to verify which entity determines prescription drug coverage for long-acting injectable antipsychotics and benefit coverage for each individual patient, based on their insurance coverage at the time they are seeking treatment. In some cases, even though a patient may be enrolled in a Managed Medicaid plan, the state retains the decision-making authority on coverage decisions for antipsychotic drugs. In other cases, the Managed Medicaid organization may be responsible for the coverage or formulary decision.

Medicare

For patients with schizophrenia who are eligible for Medicare, moving through different sites of care can mean changes in coverage for the cost of their prescriptions and medical care. Services covered in the Medicare 4-part benefit design are summarized below.

**Medicare Part A (hospital insurance):** Inpatient care for Medicare beneficiaries is covered under Medicare Part A. This covers inpatient hospital care and inpatient mental healthcare in psychiatric hospitals. Hospitals are paid by Medicare under a bundled payment that may include prescription medications, such as ARISTADA INITIO and/or ARISTADA, used during the inpatient stay.

**Medicare Part B (medical insurance):** Under Medicare Part B, medically necessary services and supplies to treat a condition or disease are covered. This also includes outpatient hospital and mental healthcare. Medicare Part B may also cover partial hospitalization by a CMHC if the HCP accepts the assignment, which could include provider-administered medications such as ARISTADA INITIO and/or ARISTADA. In these settings, healthcare professionals may be able to purchase covered medications and bill for the medication along with any related services.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Medicare Part D (outpatient prescription drugs): Medicare Part D is an optional benefit, which means that most patients must choose to enroll and pay an additional premium for coverage. All Part D plans are managed by private/commercial insurance companies; however, certain rules govern what must be covered. Under Medicare Part D, plans are required to cover all drugs in 6 “protected” drug categories, which includes schizophrenia.

Medicare Advantage (MA) and MA-PDP: MA plans are managed by private/commercial insurance companies under contract with the Centers for Medicare & Medicaid Services (CMS). Prescription drug plans that are offered as part of a Medicare Advantage plan are called Medicare Advantage–Prescription Drug Plan (MA-PDP), which may cover injectables under Medicare Part B; others may cover them under Medicare Part D.

Dual Eligibility: Medicare Part D Extra Help Low-Income Subsidy (LIS)

Patients enrolled in Medicare Part D may be eligible to receive extra help. The Extra Help program may help eligible patients reduce out-of-pocket insurance costs to as low as $1.30.

Which patients may be eligible to receive Extra Help?

In order to qualify for any level of LIS (“Extra Help”), patients must be enrolled in Medicare Part D and meet the following criteria:

Patients could be automatically enrolled and qualify for full Extra Help subsidy if:

- Patient has Medicaid
- Patient has Supplemental Social Security Income (SSI)
- Patient is in a Medicare Savings Program

OR IS ENROLLED AS

- Qualified Medicare beneficiary
- Specified low-income Medicare beneficiary
- Qualifying individual under a state’s Medicaid plan

After applying, patients receive a purple, yellow, or green letter from CMS that notifies them of their coverage.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Medicare Part D Extra Help LIS FAQs

Q: What is the difference between a full subsidy and a partial subsidy for Extra Help?
A: Patients who qualify for a full subsidy have little or no deductible, whereas patients who receive a partial subsidy may only receive 25% to 75% premium support. Co-pay amounts will also be less for patients qualifying for a full subsidy benefit.25

Q: How would a patient or caregiver know if they have Extra Help?
A: They received a purple, yellow, or green letter from CMS.

The purple letter notifies patients that they have qualified for LIS for Medicare prescription drug coverage and have been automatically enrolled in LIS without applying for it.24

The yellow letter notifies patients that they will be automatically enrolled in a LIS Medicare Prescription Drug Plan if they haven’t joined a plan on their own.26

The green letter notifies patients who get SSI benefits, patients who belong to a Medicare Savings Program, or patients who apply and qualify for LIS that they are eligible and have not yet joined a Medicare drug plan.27

If the patient did not receive a letter, they can apply at any time during the year.

Q: What are income and resource thresholds for Extra Help?
A: To qualify for either a full subsidy or a partial subsidy, patients must submit information on their income and their financial resources to ensure both are below the income and resource thresholds. The thresholds are updated annually.

2022 Eligibility Thresholds for Full or Partial Subsidy Extra Help

<table>
<thead>
<tr>
<th></th>
<th>Full Extra Help Subsidy Thresholds:</th>
<th>Partial Extra Help Subsidy Thresholds:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yearly Income²⁸</td>
<td>Married: &lt;$23,517</td>
<td>Married: &lt;$26,130</td>
</tr>
<tr>
<td></td>
<td>Single: &lt;$17,388</td>
<td>Single: &lt;$19,320</td>
</tr>
<tr>
<td>Assets²⁹</td>
<td>Married: $11,960</td>
<td>Married: $26,520</td>
</tr>
<tr>
<td></td>
<td>Single: ≤$7,970</td>
<td>Single: ≤$13,290</td>
</tr>
</tbody>
</table>

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Q: How can patients get ready to apply for Extra Help?30

A: For patients to apply, they will need to determine the monetary value of the things they own outside of their primary residence, vehicles, burial plots, life insurance policies, or personal possessions.

Patients will need to review their annual income from wages, pensions, and investments.

Finally, patients will need to gather necessary records to complete the application.

Documents that may help patients prepare include30:

- Social Security card
- Tax returns
- Payroll slips
- Bank account statements, including checking, savings, and certificates of deposit
- Individual retirement accounts, stocks, bonds, savings bonds, mutual funds, and other investment statements as applicable
- Most recent Social Security benefits award letters or statements for Railroad Retirement benefits, veteran benefits, pensions, and annuities, as applicable

Q: How can patients apply for Extra Help?

A: Patients who did not receive a purple, yellow, or green letter can submit an application at any time during the year by:

- Calling Social Security at 1-800-772-1213 to receive a paper application or to make an appointment30
- Downloading the electronic application at secure.ssa.gov/i1020/start
- Contacting their state Medicaid for assistance with applying. State Medicaid contact information can be found online at www.medicare.gov/contacts/ or by calling 1-800-MEDICARE (1-800-633-4227)31

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
For additional information, you may refer to:

Understanding Extra Help:

Extra Help Forms:
www.ssa.gov/benefits/medicare/prescriptionhelp/forms.html

Application process information:
www.ssa.gov/benefits/medicare/prescriptionhelp.html

Or call the Social Security office using the national toll-free number 1-800-772-1213 Monday to Friday, 8 AM to 7 PM.

Commercial
Most commercial insurance plans, including those offered through the healthcare exchange, or marketplace, cover professional services by healthcare providers as a standard benefit. Benefit design and coverage restrictions vary by plan, including patient co-pay, coinsurance, and deductible requirements.52

Commercial payers may cover ARISTADA INITIO and/or ARISTADA under either the medical or pharmacy benefit, or may require that ARISTADA INITIO and/or ARISTADA be obtained through a specialty pharmacy. Thoroughness during the benefit verification process can help patients obtain medications they need in a timely manner.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
PRIOR AUTHORIZATIONS, EXCEPTIONS, AND APPEALS

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
PAs, EXCEPTIONS, AND APPEALS

PA Checklist

No PA is required for ARISTADA under the pharmacy benefit for over 80% of adult patients with schizophrenia across Medicare, Medicaid, and commercial insurance plans\(^3\); however, if a benefit verification determines that a PA is required for your patient, use the checklist below to request the PA.

- ✔ If a PA is required, ask whether the plan has a product-specific PA form and where it can be obtained.
- ✔ Ask whether a PA can be submitted electronically. If it can, you can use **CoverMyMeds** to submit the completed PA.
- ✔ Obtain the phone number or fax number of the PA department.
- ✔ Ask the contact to explain the PA process and whether it requires any special forms or a letter of medical necessity.
- ✔ Inquire how long the process will take once the necessary forms and documentation are submitted.
- ✔ If the time for obtaining ARISTADA INITIO and/or ARISTADA is urgent, ask whether there are procedures for expediting the request on behalf of the patient.

\(^{a}\) Data source: DRG Fingertip Formulary as of March 2022.

Please see **Important Safety Information** on pages 4-7 and full Prescribing Information, including Boxed Warning, for **ARISTADA INITIO** and **ARISTADA**.
Formulary Exceptions

If a benefit verification determines that ARISTADA INITIO and/or ARISTADA is not covered by the patient’s insurance because the product is not on formulary, a formulary exception may be possible.33

For patients covered by Medicare, including patients with coverage under both Medicare and Medicaid (dual eligible), Part D plans are required to offer a formulary exception process.34

Appealing a Denied PA

If the healthcare professional receives a PA denial because a payer does not cover ARISTADA INITIO and/or ARISTADA, resubmit the request with additional documentation supporting medical necessity.35

If you have not done so previously, it may be appropriate to include a detailed letter of medical necessity in the appeal packet.

In addition, include a copy of the original PA request and denial notification, the patient’s complete medical history, the provider’s plan for continuing treatment, and relevant clinical information for ARISTADA INITIO and/or ARISTADA.35

If the second submission is denied, it may be necessary to contact the payer’s medical or pharmacy director.36

Appealing a Denied Claim

If a claim for treatment with ARISTADA INITIO and/or ARISTADA submitted by an office is improperly reimbursed or denied, providers may consider submitting an appeal. The checklist on the next page provides tips for appealing denied claims.
Review the Explanation of Benefits (EOB) to determine the reason for the claim denial
- If additional information is requested, submit it immediately or within the required time frame for processing

If the denial was due to a technical error, amend it and submit a corrected claim

Verify the appeals process with the payer:
- Does the payer require use of a specific form?
- Can the appeal be conducted over the phone?
- If the appeal must be submitted in writing, to whom should it be directed?
- What information must be included with the appeal (e.g., copy of the original claim, EOB, letter of medical necessity, or other documentation)?
- How long does the appeals process usually take?
- How will the payer communicate the appeals decision?

Review the appeal request for accuracy and completeness, including patient ID numbers and coding

Request that a psychiatrist or other designated provider who is familiar with treating patients with ARISTADA INITIO and/or ARISTADA review the appeal

File the appeal as soon as possible and within filing time limits

Reconcile responses to the appeal promptly and thoroughly to ensure an appeal has been processed appropriately

Record appeals result (e.g., payment amount or if further action is required)

The specific processes, levels of appeal, and timelines vary by payer. CMS has a defined process for appeals of both original Medicare, MA, and Part D coverage decisions. Both follow a similar 5-level structure, with specific deadlines and time limits for both standard and expedited requests. If there is concern that a patient could be harmed by waiting the standard 14 days for a decision, a healthcare professional can request an expedited decision within 72 hours. For additional information and required forms for Medicare, please visit the CMS website.

For additional questions about PAs, formulary exceptions, and appeals, please contact ARISTADA Care Support at 1-866-ARISTADA (1-866-274-7823) or online at www.aristadacaresupport.com.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
PROCUREMENT AND ORDERING

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Pathways for Obtaining ARISTADA INITIO and/or ARISTADA

Always check with each payer prior to ordering or administering ARISTADA INITIO and/or ARISTADA to verify patient-specific requirements.

1 Order and submit a claim (buy and bill)

This acquisition method allows a site of care the ability to purchase medications such as ARISTADA INITIO and/or ARISTADA for healthcare professional administration to patients. ARISTADA Care Support can help with the benefit verification process to confirm the patient’s coverage for ARISTADA INITIO and/or ARISTADA if the practice prefers to buy and bill.

2 Specialty pharmacy provider (SPP)

This option enables an SPP to purchase ARISTADA INITIO and/or ARISTADA for delivery and administration at a site of care. ARISTADA Care Support is available to assist in coordinating delivery through an available SPP based on the patient’s insurance coverage and any payer-specific rules regarding use of in-network SPPs. ARISTADA Care Support can confirm shipment and delivery of ARISTADA INITIO and/or ARISTADA to the site for the identified patient.

3 Retail pharmacy

Check with the providing retail pharmacy if they offer delivery of ARISTADA INITIO and/or ARISTADA to your site of care.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
ORDERING INFORMATION FOR ARISTADA INITIO

ARISTADA INITIO can be ordered from the following sources:

<table>
<thead>
<tr>
<th>Wholesaler/Distributor</th>
<th>Phone</th>
<th>ARISTADA INITIO</th>
</tr>
</thead>
<tbody>
<tr>
<td>AmerisourceBergen</td>
<td>1-610-727-7000</td>
<td>675 mg Item #</td>
</tr>
<tr>
<td>McKesson</td>
<td>1-800-793-9875</td>
<td>10188766</td>
</tr>
<tr>
<td>Cardinal</td>
<td>1-800-926-3161</td>
<td>3919800</td>
</tr>
<tr>
<td>HD Smith</td>
<td>1-866-232-1222</td>
<td>5464953</td>
</tr>
<tr>
<td>Kinray</td>
<td>1-888-527-6806</td>
<td>572-6302</td>
</tr>
<tr>
<td>Smith Drug/Burlington</td>
<td>1-800-542-1216</td>
<td>734984</td>
</tr>
<tr>
<td>Rochester Drug</td>
<td>1-800-333-0538</td>
<td>853168</td>
</tr>
<tr>
<td>Value Drug</td>
<td>1-800-252-3786</td>
<td>10772333</td>
</tr>
<tr>
<td>Morris &amp; Dickson</td>
<td>1-800-388-3833</td>
<td>194844</td>
</tr>
<tr>
<td>Dakota Drug</td>
<td>1-866-210-5887</td>
<td>380865</td>
</tr>
<tr>
<td>N.C. Mutual Drug</td>
<td>1-800-800-8551</td>
<td>390831</td>
</tr>
<tr>
<td>ANDA Inc.</td>
<td>1-800-331-2632</td>
<td>318949</td>
</tr>
<tr>
<td>Louisiana Wholesale</td>
<td>1-800-960-3784</td>
<td>804692</td>
</tr>
<tr>
<td>R&amp;S Northeast</td>
<td>1-800-262-7770</td>
<td>210237</td>
</tr>
<tr>
<td>Prescription Supply</td>
<td>1-800-777-0761</td>
<td>050003a</td>
</tr>
</tbody>
</table>

*Not stocked but will order on demand.

To order ARISTADA INITIO, contact your wholesaler/distributor.
For product information, call 1-866-ARISTADA (1-866-274-7823) or visit www.ARISTADAhcp.com.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
ORDERING INFORMATION FOR ARISTADA

ARISTADA can be ordered from the following sources:

<table>
<thead>
<tr>
<th>Wholesaler/Distributor</th>
<th>Phone</th>
<th>441 mg Item #</th>
<th>622 mg Item #</th>
<th>882 mg Item #</th>
<th>1064 mg Item #</th>
</tr>
</thead>
<tbody>
<tr>
<td>AmerisourceBergen</td>
<td>1-610-727-7000</td>
<td>10158930</td>
<td>10158907</td>
<td>10158906</td>
<td>10178590</td>
</tr>
<tr>
<td>McKesson</td>
<td>1-800-793-9875</td>
<td>3489051</td>
<td>3489069</td>
<td>3489077</td>
<td>3670726</td>
</tr>
<tr>
<td>Cardinal</td>
<td>1-800-926-3161</td>
<td>5161427</td>
<td>5161492</td>
<td>5161567</td>
<td>5368352</td>
</tr>
<tr>
<td>HD Smith</td>
<td>1-866-232-1222</td>
<td>551-7206</td>
<td>551-7214</td>
<td>551-7222</td>
<td>566-8843</td>
</tr>
<tr>
<td>Kinray</td>
<td>1-888-527-6806</td>
<td>411169</td>
<td>411177</td>
<td>411195</td>
<td>5368352</td>
</tr>
<tr>
<td>Smith Drug/Burlington</td>
<td>1-800-542-1216</td>
<td>741918</td>
<td>741900</td>
<td>741926</td>
<td>809780</td>
</tr>
<tr>
<td>Rochester Drug</td>
<td>1-800-333-0538</td>
<td>10698942</td>
<td>10698959</td>
<td>10698967</td>
<td>10737922</td>
</tr>
<tr>
<td>Value Drug</td>
<td>1-800-252-3786</td>
<td>146044</td>
<td>146048</td>
<td>146046</td>
<td>175878</td>
</tr>
<tr>
<td>Morris &amp; Dickson</td>
<td>1-800-388-3833</td>
<td>398776</td>
<td>398834</td>
<td>399311</td>
<td>981852</td>
</tr>
<tr>
<td>Dakota Drug</td>
<td>1-866-210-5887</td>
<td>262188</td>
<td>262204</td>
<td>262212</td>
<td>312314</td>
</tr>
<tr>
<td>N.C. Mutual Drug</td>
<td>1-800-800-8551</td>
<td>195024</td>
<td>195032</td>
<td>195040</td>
<td>270538</td>
</tr>
<tr>
<td>ANDA Inc.</td>
<td>1-800-331-2632</td>
<td>804348</td>
<td>804349</td>
<td>804350</td>
<td>804531</td>
</tr>
<tr>
<td>Louisiana Wholesale</td>
<td>1-800-960-3784</td>
<td>166165</td>
<td>166173</td>
<td>166181</td>
<td>189589</td>
</tr>
<tr>
<td>R&amp;S Northeast</td>
<td>1-800-262-7770</td>
<td>040103*</td>
<td>040203*</td>
<td>0403030*</td>
<td>040403*</td>
</tr>
<tr>
<td>Prescription Supply</td>
<td>1-800-777-0761</td>
<td>962886</td>
<td>961599</td>
<td>958892</td>
<td>962902</td>
</tr>
</tbody>
</table>

* Not stocked but will order on demand.

To order ARISTADA, contact your wholesaler/distributor. For product information, call 1-866-ARISTADA (1-866-274-7823) or visit www.ARISTADAHcp.com.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
DOSING AND ADMINISTRATION
ARISTADA INITIO reduces oral aripiprazole supplementation to 1 day

ARISTADA INITIO is only to be used as a single dose to initiate ARISTADA treatment or as a single dose to re-initiate ARISTADA treatment following a missed dose of ARISTADA. ARISTADA INITIO is not for repeated dosing.

**Important dosing considerations**

- ARISTADA INITIO and ARISTADA are not interchangeable because of differing pharmacokinetic profiles
- ARISTADA INITIO and ARISTADA are only to be administered as an intramuscular injection by a healthcare professional

Please see important dosing considerations continued on next page.

Please see **Important Safety Information** on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Important dosing considerations (cont’d)

• For patients who have never taken aripiprazole, establish tolerability with oral aripiprazole prior to initiating ARISTADA or ARISTADA INITIO1,2

• ARISTADA INITIO can be administered in the deltoid or gluteal muscle.1 Administer ARISTADA intramuscular injection in the gluteal muscle (all doses) or deltoid muscle (441 mg dose only).2 Avoid injecting both ARISTADA and ARISTADA INITIO concomitantly into the same deltoid or gluteal muscle1,2

• ARISTADA INITIO is only available at a single strength as a single-dose pre-filled syringe, so dosage adjustments are not possible. Therefore, 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 benzodiazepines1

• There are two ways to start treatment with ARISTADA. If not starting ARISTADA with ARISTADA INITIO, administer 21 consecutive days of oral aripiprazole with the first ARISTADA injection2

• In pharmacokinetic studies, the safety profile of ARISTADA INITIO was generally consistent with that observed for ARISTADA. The most common adverse reaction in patients treated with aripiprazole lauroxil was akathisia1

• Once stabilized on ARISTADA, for patients taking strong CYP2D6 inhibitors, strong CYP3A4 inhibitors, or strong CYP3A4 inducers2:
  - No dosage changes are recommended for ARISTADA if CYP450 modulators are added for <2 weeks
  - Dose changes to ARISTADA are required if CYP450 modulators are added for >2 weeks

• Depending on the ARISTADA dose, adjustments may be recommended. Refer to the information in table 4 of the full Prescribing Information for ARISTADA for dose adjustments with concomitant CYP450 modulator use2

• When any dose of ARISTADA is missed, administer the next injection as soon as possible. Concomitant supplementation following a missed dose may be recommended depending on the time elapsed since the last injection. See the full Prescribing Information for more information2

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
ARISTADA can be started at any dose\(^2\)

**DAY 1**

**STEP 1**
After establishing tolerability with oral aripiprazole, give patients a *one-time* ARISTADA INITIO injection and a single 30 mg dose of oral aripiprazole\(^1\)

*ONE ARISTADA INITIO DOSE AND A SINGLE 30 MG DOSE OF ORAL ARIPIPRAZOLE*

**STEP 2**
Select *one* ARISTADA dose and give on the same day or up to 10 days later, if desired\(^2\)

441 mg  662 mg  882 mg  1064 mg

*FIRST ARISTADA DOSE*

**Dosing intervals for ARISTADA\(^2\)**

<table>
<thead>
<tr>
<th>Dose</th>
<th>Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARISTADA 1064 MG</td>
<td>EVERY 2 MONTHS</td>
</tr>
<tr>
<td>ARISTADA 882 MG</td>
<td>EVERY 6 WEEKS</td>
</tr>
<tr>
<td>ARISTADA 882 MG</td>
<td>MONTHLY</td>
</tr>
<tr>
<td>ARISTADA 662 MG</td>
<td>MONTHLY</td>
</tr>
<tr>
<td>ARISTADA 441 MG</td>
<td>MONTHLY</td>
</tr>
</tbody>
</table>

The *2-month dose* (1064 mg) provides the longest dosing interval of ARISTADA.

Please see *Important Safety Information* on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Select all 3 components when starting ARISTADA

Example illustrates prescribing ARISTADA INITIO and ARISTADA 2-month dose

- **Initiation regimen**: Select option
  - 30 mg oral aripiprazole on day 1
- **Initiation regimen**: Select option
  - ARISTADA INITIO 675 mg on day 1
- **ARISTADA dose**: Select option
  - ARISTADA 441 mg monthly
  - ARISTADA 662 mg monthly
  - ARISTADA 882 mg every 6 weeks or monthly
  - ARISTADA 1064 mg every 2 months

This part of the initiation regimen is to be administered only once (Day 1)

If not starting with ARISTADA INITIO, administer 21 consecutive days of oral aripiprazole in conjunction with the first ARISTADA injection.²

This guide does not contain all of the information needed to administer ARISTADA INITIO and/or ARISTADA. Please refer to the full Prescribing Information and package labeling for additional instruction on dosing and administration, and Instructions for Use.

---

¹ The ARISTADA INITIO regimen is defined as a single injection of ARISTADA INITIO (675 mg) given in conjunction with a single 30 mg dose of oral aripiprazole.³

² Administer future ARISTADA injections according to approved dosing interval.

Please see **Important Safety Information** on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
# HOW SUPPLIED

## ARISTADA INITIO

<table>
<thead>
<tr>
<th>NDC</th>
<th>Dose</th>
<th>Quantity</th>
</tr>
</thead>
</table>
| 65757-0500-03  | The 675 mg strength kit (gray label) contains 3 safety needles:  
|                | • 1-inch (25 mm) 21 gauge  
|                | • 1½-inch (38 mm) 20 gauge  
|                | • 2-inch (50 mm) 20 gauge                  | 1 kit    |

## ARISTADA

<table>
<thead>
<tr>
<th>NDC</th>
<th>Dose</th>
<th>Quantity</th>
</tr>
</thead>
</table>
| 65757-0401-03  | The 441 mg strength kit (light blue label) contains 3 safety needles:  
|                | • 1-inch (25 mm) 21 gauge  
|                | • 1½-inch (38 mm) 20 gauge  
|                | • 2-inch (50 mm) 20 gauge                  | 1 kit    |
| 65757-0402-03  | The 662 mg strength kit (green label) contains 2 safety needles:  
|                | • 1½-inch (38 mm) 20 gauge  
|                | • 2-inch (50 mm) 20 gauge                  | 1 kit    |
| 65757-0403-03  | The 882 mg strength kit (burgundy label) contains 2 safety needles:  
|                | • 1½-inch (38 mm) 20 gauge  
|                | • 2-inch (50 mm) 20 gauge                  | 1 kit    |
| 65757-0404-03  | The 1064 mg strength kit (dark blue label) contains 2 safety needles:  
|                | • 1½-inch (38 mm) 20 gauge  
|                | • 2-inch (50 mm) 20 gauge                  | 1 kit    |

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Storage Information

Store each product properly per instructions on carton(s).

**ARISTADA INITIO Storage¹**

ARISTADA INITIO should be stored at room temperature 20°C to 25°C (68°F to 77°F) with excursions permitted between 15°C and 30°C (between 59°F and 86°F). **Do not freeze.**

ARISTADA INITIO cartons should lay flat when stored and should not be shelved vertically. The carton is shaped to assist with proper storage. Proper storage of ARISTADA INITIO should help prevent excessive sedimentation near the needle hub.³

**ARISTADA Storage²**

ARISTADA should be stored at room temperature 20°C to 25°C (68°F to 77°F) with excursions permitted between 15°C and 30°C (between 59°F and 86°F).
PROVIDER OFFICE
OR CMHC

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
CODING FOR ARISTADA INITIO AND ARISTADA

When submitting claims for a patient's treatment with ARISTADA INITIO and/or ARISTADA, it is important to use codes that accurately reflect the patient's condition, treatment, and other services rendered. Different coding systems are used to describe a patient's medical condition, the drugs administered, and services provided. Submission of claims with inaccurate or incomplete codes may result in delayed or incorrect payment or denial of claims. This section describes the ARISTADA INITIO and/or ARISTADA code sets.

The 837P (Professional) is the standard format used by healthcare professionals and suppliers to transmit claims electronically. The CMS-1500 form is the standard paper claim form used to bill most insurance carriers, including Medicare, Medicaid, and commercial carriers when a paper claim is allowed. Data elements in the CMS uniform electronic billing specifications for 837P are consistent with the hard copy data set.41

Healthcare professionals and other qualified providers should submit all electronic claims using the 837P claims format, following ANSI ASC X12N 837P Version 5010A1 electronic data interchange transaction standards. Healthcare professionals who treat Medicare beneficiaries may use the CMS-1500 form (version 02/12) for most payers who accept paper claims if a paper claim is necessary.41,42

The following information highlights some of the key product-specific fields in the 837P and the coordinating location on the CMS-1500 for Medicare claims reporting purposes. Please check with other payers for specific details and processes for use of appropriate forms.

IMPORTANT: Healthcare providers are responsible for keeping current and complying with all applicable coverage requirements and for the selection of diagnosis and procedure codes that accurately reflect their patient's condition and the services rendered. Healthcare providers also are responsible for the accuracy of all claims and related documentation submitted for reimbursement. Additional insurance requirements may apply and healthcare providers should always contact the insurer directly to obtain complete and current information regarding coverage of ARISTADA and/or ARISTADA INITIO. Alkermes does not guarantee coverage or reimbursement. Under no circumstances will Alkermes, Inc., or its affiliates, employees, consultants, agents or representatives be liable for costs, expenses, losses, claims, liabilities or other damages that may arise from, or be incurred in connection with, the information provided here or any use thereof.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Coding decisions should be made by the physician based on an independent review of the patient’s condition.

**Quick Reference Table for CMS-1500/837P**

<table>
<thead>
<tr>
<th>Field/category name</th>
<th>ARISTADA INITIO</th>
<th>ARISTADA</th>
<th>837P loop ID, segment/data element</th>
<th>CMS-1500 (02/12) field number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedures, services, or supplies NDC</td>
<td>675 mg: NDC 65757-0500-03 Note: The NDC goes in the shaded area above the J-code line, justified left above Item 24A</td>
<td>441 mg: NDC 65757-0401-03 662 mg: NDC 65757-0402-03 882 mg: NDC 65757-0403-03 1064 mg: NDC 65757-0404-03</td>
<td>Loop 2400/ SV101</td>
<td>Item 24D</td>
</tr>
<tr>
<td>Procedures, services, or supplies (eg, CPT code)</td>
<td>96372 Therapeutic, prophylactic, or diagnostic injection</td>
<td>96372 Therapeutic, prophylactic, or diagnostic injection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedures, services, or supplies HCPCS</td>
<td>J1943 Injection, aripiprazole lauroxil, (ARISTADA INITIO), 1 mg</td>
<td>J1944 Injection, aripiprazole lauroxil, (ARISTADA), 1 mg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Units</td>
<td>675 billing units for 675 mg • 441 billing units for 441 mg • 662 billing units for 662 mg • 882 billing units for 882 mg • 1064 billing units for 1064 mg</td>
<td></td>
<td>Loop 2400/ SV104</td>
<td>Item 24G</td>
</tr>
<tr>
<td>Diagnosis or nature of illness or injury ICD-10-CM</td>
<td>Input appropriate diagnosis code 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 Unspecified schizophrenia</td>
<td></td>
<td>Loop 2300/ H101-2 to H112-2</td>
<td>Item 21</td>
</tr>
<tr>
<td>Place of service</td>
<td>11 Physician Office 53 Community Mental Health Center</td>
<td></td>
<td>Loop 2300/ CLM05-1 Loop 2400/ SV105</td>
<td>Item 24B</td>
</tr>
</tbody>
</table>


All examples indicated should also include any placeholder digits required by the 837P format.

CPT® is a registered trademark of the American Medical Association.

Other codes may be appropriate for billing for ARISTADA INITIO and/or ARISTADA. Depending on the site of care, providers may need to use a variety of codes to bill for other types of services provided to a patient. Rules regarding coverage and payment for services vary according to payer and should be verified before submitting claims.

**Note:** Payer policy may vary on requirements for billing two separate drug injections on the same date. Please review individual payer policy. Generally, modifier 59 is utilized with the second injection procedure code on the CMS-1500 claim form.

- This code is not intended to be reported by the physician in the facility setting.
- ARISTADA INITIO and/or ARISTADA are administered as intramuscular injections only.

Please see **Important Safety Information** on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
**SAMPLE CLAIM FORMS**

Checklist for submitting electronic or paper provider office/CMHC claims for ARISTADA INITIO and/or ARISTADA

Prior to treatment or submitting a claim, ensure that all payer requirements for coverage are met, such as:

**Letter of medical necessity, if needed**
- ✔ Include documentation, as needed, if a step edit exists
- ✔ Attach prescribing information

**Claim form completion and submission**
- ✔ Use the claim form and preferred format (eg, electronic or paper) designated by the payer
- ✔ Identify correct dates of service
- ✔ Provide correct and accurate coding
- ✔ Correctly specify number of billing units
- ✔ Provide the full documentation required by the payer including healthcare professional order, if requested
- ✔ Ensure documentation includes a valid and legible healthcare professional signature or acceptable e-signature
- ✔ Submit claim within the payer’s designated claim filing time frame

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
ARISTADA INITIO and ARISTADA Same Day Administration

Physician Office

Recording Drug Administration

• ARISTADA INITIO and ARISTADA may be administered on the same day
• This billing form is an example of when drug administration happens on the same date. ARISTADA INITIO 675 mg and ARISTADA 662 mg is administered on MMDDYY

Item 21 Diagnosis: Enter the appropriate ICD-10-CM diagnosis code for the principal diagnosis for the encounter

(*) = specific 4th–5th digit required; final code depends on medical record documentation

Item 24D Procedures/Services/Supplies: Enter appropriate CPT/HCPCS codes and Modifiers;
• Drug: J1943 for ARISTADA INITIO; J1944 for ARISTADA
• Administration: 96372 for IM injection

Item 24E Diagnosis Pointer: Enter the letter (A-J) that corresponds to the diagnosis in Item 21

Item 24A: Enter the NDC in the shaded area above the date of service line (qualifier N4 should precede the 11-digit NDC)
• ARISTADA INITIO N465757050003 for 675 mg
• ARISTADA N465757040203 for a 662 mg injection

Item 24B Place of Service: Enter the appropriate place of service code

Item 24G Units: Enter the appropriate billing units for each line item. When billing ARISTADA INITIO and ARISTADA, 1 billing unit is equal to 1 mg

ARISTADA
• 441 billing units for 441 mg
• 662 billing units for 662 mg
• 882 billing units for 882 mg
• 1064 billing units for 1064 mg

ARISTADA INITIO
• 675 billing units for 675 mg

Note: Enter 2 units for administration of ARISTADA and ARISTADA INITIO

This information is for example purposes and payer coding and billing requirements may vary. Please refer to payer guidance for specific claim form submission or specific coding use.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
ARISTADA INITIO and ARISTADA Different Day Administration

Physician Office

Recording Drug Administration

- The first ARISTADA injection may be administered up to 10 days after ARISTADA INITIO
- This billing form is an example of when drug administration happens on different dates within an inpatient stay. ARISTADA INITIO 675 mg is administered on 11/01/21, while ARISTADA 662 mg is administered on 11/08/21

```
Item 21 Diagnosis: Enter the appropriate ICD-10-CM diagnosis code for the principal diagnosis for the encounter
(* = specific 4th–5th digit required; final code depends on medical record documentation)

Item 24D Procedures/Services/Supplies: Enter appropriate CPT/HCPCS codes and Modifiers;
- Drug: J1943 for ARISTADA INITIO; J1944 for ARISTADA
- Administration: 96372 for IM injection

Item 24E Diagnosis Pointer: Enter the letter (A-J) that corresponds to the diagnosis in Item 21

Item 24A: Enter the NDC in the shaded area above the date of service line (qualifier N4 should precede the 11-digit NDC)
- ARISTADA INITIO N465757050003 for 675 mg
- ARISTADA N465757040203 for a 662 mg injection

Item 24B Place of Service: Enter the appropriate place of service code

Item 24G Units: Enter the appropriate billing units for each line item. When billing ARISTADA INITIO and ARISTADA, 1 billing unit is equal to 1 mg
- ARISTADA
  - 441 billing units for 441 mg
  - 662 billing units for 662 mg
  - 882 billing units for 882 mg
  - 1064 billing units for 1064 mg
- ARISTADA INITIO
  - 675 billing units for 675 mg

This information is for example purposes and payer coding and billing requirements may vary. Please refer to payer guidance for specific claim form submission or specific coding use.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
**ARISTADA Only** Administration

**Physician Office**

Recording Drug Administration

- Following is an example of billing forms when ARISTADA 662 mg is administered only.

**Item 21 Diagnosis:** Enter the appropriate ICD-10-CM diagnosis code for the principal diagnosis for the encounter

(* = specific 4th–5th digit required; final code depends on medical record documentation)

**Item 24D Procedures/Services/Supplies:** Enter appropriate CPT/HCPCS codes and Modifiers:

- Drug: J1944 for ARISTADA
- Administration: 96372 for IM injection

**Item 24E Diagnosis Pointer:** Enter the letter (A-J) that corresponds to the diagnosis in Item 21

**Item 24A:** Enter the NDC in the shaded area above the date of service line (qualifier N4 should precede the 11-digit NDC)

- ARISTADA N465757040203 for a 662 mg injection

**Item 24B Place of Service:** Enter the appropriate place of service code

**Item 24G Units:** Enter the appropriate billing units for each line item. When billing ARISTADA, 1 billing unit is equal to 1 mg

- ARISTADA
  - 441 billing units for 441 mg
  - 662 billing units for 662 mg
  - 882 billing units for 882 mg
  - 1064 billing units for 1064 mg

This information is for example purposes and payer coding and billing requirements may vary. Please refer to payer guidance for specific claim form submission or specific coding use.

Please see **Important Safety Information** on pages 4-7 and full Prescribing Information, including Boxed Warning, for **ARISTADA INITIO** and **ARISTADA**.
COMPLETING THE CMS-1500 CLAIM FORM

1. Item 21 - Enter the appropriate ICD-10-CM code for the principal diagnosis for the encounter

2. Item 24A - Enter the NDC in the shaded area above the date of service line (qualifier N4 should precede the 11-digit NDC)
   a. ARISTADA INITIO N465757050003
   b. ARISTADA N465757040203 for a 662 mg injection

3. Item 24B - Enter the appropriate place of service code

4. Item 24D - Enter the appropriate HCPCS codes. ARISTADA INITIO may be reported with J1943, ARISTADA may be reported with J1944, administration may be reported with 96372

5. Item 24E - Enter the letter (A–J) that corresponds to the diagnosis in Item 21

6. Item 24G - Enter the appropriate billing units for each line item. When billing ARISTADA INITIO and ARISTADA, 1 billing unit is equal to 1 mg
   a. ARISTADA
      i. 441 billing units for 441 mg
      ii. 662 billing units for 662 mg
      iii. 882 billing units for 882 mg
      iv. 1064 billing units for 1064 mg
   b. ARISTADA INITIO
      i. 675 billing units for 675 mg

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
REIMBURSEMENT CONSIDERATIONS

Definition of a CMHC May Vary by Payer

Understanding how each patient’s insurance company recognizes or classifies a CMHC is an essential step in understanding how treatment with ARISTADA INITIO and/or ARISTADA may be covered and reimbursed.

Coverage for ARISTADA INITIO and/or ARISTADA administered in a CMHC or provider’s office varies by payer type.

State Medicaid programs use a variety of reimbursement methods, including fee schedules or other predetermined rates. Reimbursement for drugs is separate from professional services and may be based on wholesale acquisition cost (WAC), invoice cost, average sales price (ASP), average wholesale price (AWP), or other formulas as determined by the individual payer. Contact the state Medicaid program for more information about state-specific coverage for ARISTADA INITIO and/or ARISTADA in the CMHC or provider office.

Patients covered by Medicare plans, including those who qualify for benefits under Medicare and Medicaid, may have coverage for ARISTADA INITIO and/or ARISTADA under either Part D or Part B. Reimbursement for drugs under Part B is generally based on ASP. Coverage of ARISTADA INITIO and/or ARISTADA under Part D will vary by plan, depending on formulary and benefit design.

Commercial plans use a variety of reimbursement methods, including fee schedules, discounted charges, or other predetermined rates. Reimbursement for drugs is separate from professional services and may be based on WAC, AWP, billed charges, ASP, or other payer-specific methodologies. Contact the commercial plan or review the payer contract for more information about specific coverage for ARISTADA INITIO and/or ARISTADA in the CMHC or provider office.

* For Medicare billing purposes, this section refers to CMHCs that function as a clinic and are not certified by Medicare to provide partial hospitalization services.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
HOPD OR PARTIAL HOSPITALIZATION
CMHCs

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
CODING FOR ARISTADA INITIO AND ARISTADA

When submitting claims for a patient’s treatment with ARISTADA INITIO and/or ARISTADA, it is important to use codes that accurately reflect the patient’s condition, treatment, and other services rendered. Different coding systems are used to describe a patient’s medical condition, the drugs administered, and services provided. Submission of claims with inaccurate or incomplete codes may result in delayed or incorrect payment or denial of claims. This section describes the ARISTADA INITIO and/or ARISTADA code sets.

The 837I (Institutional) is the standard format used by institutional providers to transmit claims electronically.\textsuperscript{53}

The form UB-04, also known as the CMS-1450, is the standard claim form to bill Medicare Administrative Contractors when a paper claim is allowed. Data elements in the CMS uniform electronic billing specifications for 837I are consistent with the hard copy data set.\textsuperscript{53}

The 837I and UB-04 also may be suitable for billing various government and some commercial insurers. Please check with Medicaid programs and private payers for specific details and processes.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Coding decisions should be made by the physician based on an independent review of the patient’s condition.

### Quick Reference Table for UB-04/CMS-1450/837I

<table>
<thead>
<tr>
<th>Field/category name</th>
<th>ARISTADA INITIO&lt;sup&gt;1,43-45,54&lt;/sup&gt;</th>
<th>ARISTADA&lt;sup&gt;2,43-45,54&lt;/sup&gt;</th>
<th>837I loop ID, segment/data element&lt;sup&gt;55&lt;/sup&gt;</th>
<th>UB-04/CMS-1450&lt;sup&gt;55&lt;/sup&gt;</th>
</tr>
</thead>
</table>
| **Revenue code**    | • Medicare, revenue code 0636 (drugs that require detailed coding)  
• For non-Medicare payers, revenue code 0250 (general pharmacy)  
• Injection services may be reported with revenue code 0510 (clinic, general service) or 0940 (other therapeutic services, general) | | Loop 2400, SV201 | Field 42 |
| **Procedures, services, or supplies** | 675 mg: NDC 65757-0500-03  
662 mg: NDC 65757-0402-03  
882 mg: NDC 65757-0403-03  
1064 mg: NDC 65757-0404-03 | Check with payer (instructions may vary) | | Field 43 |
| **Procedures, services, or supplies** | 96372 Therapeutic, prophylactic, or diagnostic injection<sup>b</sup> | | | |
| **Procedures, services, or supplies** | J1943 Injection, aripiprazole lauroxil, (ARISTADA INITIO), 1 mg  
J1944 Injection, aripiprazole lauroxil, (ARISTADA), 1 mg | | Loop 2400, SV202-2 | Field 44 |
| **Units** | 675 billing units for 675 mg  
441 billing units for 441 mg  
662 billing units for 662 mg  
882 billing units for 882 mg  
1064 billing units for 1064 mg | | Loop 2400, SV205 | Field 46 |
| **Diagnosis or nature of illness or injury** | Input appropriate diagnosis code  
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 Unspecified schizophrenia | | Loop 2300, H101-2 (H101-1=BK) | Fields 67A-Q |


CPT<sup>®</sup> is a registered trademark of the American Medical Association.

Other codes may be appropriate for billing for ARISTADA INITIO and/or ARISTADA. Depending on the site of care, providers may need to use a variety of codes to bill for other types of services provided to a patient. Rules regarding coverage and payment for services vary according to payer and should be verified before submitting claims.

**Note:** Payer policy may vary on requirements for billing two separate drug injections on the same date. Please review individual payer policy.

<sup>a</sup> This code is not intended to be reported by the physician in the facility setting.

<sup>b</sup> ARISTADA INITIO and/or ARISTADA are administered as intramuscular injections only.<sup>1,2</sup>

Please see **Important Safety Information** on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
SAMPLE CLAIM FORMS

Checklist for submitting electronic or paper hospital claims for ARISTADA INITIO and/or ARISTADA

Prior to treatment or submitting a claim, ensure that all payer requirements for coverage are met, such as:

**Letter of medical necessity, if needed**
- ✓ Include documentation, as needed, if a step edit exists
- ✓ Attach prescribing information

**Claim form completion and submission**
- ✓ Use the claim form and preferred format (eg, electronic or paper) designated by the payer
- ✓ Identify correct dates of service
- ✓ Provide correct and accurate coding
- ✓ Correctly specify number of billing units
- ✓ Provide the full documentation required by the payer including healthcare professional order, if requested
- ✓ Ensure documentation includes a valid and legible healthcare professional signature or acceptable e-signature
- ✓ Submit claim within the payer’s designated claim filing time frame

Please see **Important Safety Information** on pages **4-7** and full Prescribing Information, including Boxed Warning, for **ARISTADA INITIO** and **ARISTADA**.
ARISTADA INITIO and ARISTADA Same Day Administration

Hospital Outpatient Department (HOPD)

Recording Drug Administration

- ARISTADA INITIO and ARISTADA may be administered on the same day.
- This billing form is an example of when drug administration happens on the same date. ARISTADA INITIO 675 mg and ARISTADA 662 mg is administered on MMDDYY.

Field 42-43: Enter the appropriate revenue code and description corresponding to the HCPCS code in field 44.
- 0636 for ARISTADA and ARISTADA INITIO
- 0510 for IM injection administered in the HOPD

Note: Other revenue codes may apply

Field 44: Enter appropriate CPT/HCPCS codes and modifiers.
- Drug: J1943 for ARISTADA INITIO; J1944 for ARISTADA
- Administration: 96372 for IM injection

Field 46: Enter the appropriate number of units for each line item. When billing ARISTADA INITIO and/or ARISTADA, 1 billing unit is equal to 1 mg.

ARISTADA:
- 441 billing units for 441 mg
- 662 billing units for 662 mg
- 882 billing units for 882 mg
- 1064 billing units for 1064 mg

ARISTADA INITIO:
- 675 billing units for 675 mg

Note: Enter 2 units for administration of ARISTADA and ARISTADA INITIO.

Field 67 and 67A-67Q: Enter the appropriate ICD-10-CM diagnosis code for the principal diagnosis for the encounter.

(*) = specific 4th–5th digit required; final code depends on medical record documentation.

Note: Other diagnoses codes may apply

This information is for example purposes and payer coding and billing requirements may vary. Please refer to payer guidance for specific claim form submission or specific coding use.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
ARISTADA INITIO and ARISTADA Different Day Administration

HOPD

Recording Drug Administration

• The first ARISTADA injection may be administered up to 10 days after ARISTADA INITIO.
• This billing form is an example of when drug administration happens on different dates within an inpatient stay. ARISTADA INITIO 675 mg is administered on 11/01/21, while ARISTADA 662 mg is administered on 11/08/21.

Field 42-43: Enter the appropriate revenue code and description corresponding to the HCPCS code in field 44.
• 0636 for ARISTADA and ARISTADA INITIO
• 0510 for IM injection administered in the HOPD

Note: Other revenue codes may apply

Field 44: Enter appropriate CPT/HCPCS codes and modifiers.
• Drug: J1943 for ARISTADA INITIO; J1944 for ARISTADA
• Administration: 96372 for IM injection

Field 67 and 67A-67Q: Enter the appropriate ICD-10-CM diagnosis code for the principal diagnosis for the encounter.
(* = specific 4th-5th digit required; final code depends on medical record documentation)

This information is for example purposes and payer coding and billing requirements may vary. Please refer to payer guidance for specific claim form submission or specific coding use.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
ARISTADA Only Administration

HOPD

Recording Drug Administration

- Following is an example of billing forms when ARISTADA 662 mg is administered only.

Field 42-43: Enter the appropriate revenue code and description corresponding to the HCPCS code in field 44
- 0636 for ARISTADA
- 0510 for IM injection administered in the HOPD

Note: Other revenue codes may apply

Field 44: Enter appropriate CPT/HCPCS codes and modifiers
- Drug: J1944 for ARISTADA
- Administration: 96372 for IM injection

Field 46: Enter the appropriate number of units for each line item. When billing ARISTADA, 1 billing unit is equal to 1 mg
ARISTADA
- 441 billing units for 441 mg
- 662 billing units for 662 mg
- 882 billing units for 882 mg
- 1064 billing units for 1064 mg

Field 67 and 67A-67Q: Enter the appropriate ICD-10-CM diagnosis code for the principal diagnosis for the encounter
(* = specific 4th-5th digit required; final code depends on medical record documentation)

This information is for example purposes and payer coding and billing requirements may vary. Please refer to payer guidance for specific claim form submission or specific coding use.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
COMPLETING THE CMS-1450 CLAIM FORM

1. **Field 42** - Enter the appropriate revenue code. ARISTADA and ARISTADA INITIO may be reported with 0636 (drugs requiring detailed coding) or 0250 (pharmacy, general), and the administration may be reported with 0510 (clinic, general) or 0940 (other therapeutic services, general). Other revenue codes may apply, check individual payer requirements.

2. **Field 43** - Enter the description of corresponding HCPCS code listed in field 44 (field 43)
   - a. Enter the NDC in field 43
      - i. Qualifier N4 should be added before the 11-digit NDC
         - 1. ARISTADA INITIO N465757050003
         - 2. ARISTADA N465757040203 for a 662 mg injection
   - b. Check individual payer requirements for additional NDC reporting requirements (ie unit of measure and quantity of drug)

3. **Field 44** - Enter the appropriate CPT/HCPCS code. ARISTADA INITIO may be reported with HCPCS code J1943, ARISTADA may be reported with HCPCS code J1944, administration may be reported with CPT 96372.

4. **Field 46** - Enter the appropriate billing units for each line item. When billing ARISTADA INITIO and/or ARISTADA, 1 billing unit is equal to 1 mg
   - a. ARISTADA
      - i. 441 billing units for 441 mg
      - ii. 662 billing units for 662 mg
      - iii. 882 billing units for 882 mg
      - iv. 1064 billing units for 1064 mg
   - b. ARISTADA INITIO
      - i. 675 billing units for 675 mg

5. **Field 67** - Enter the appropriate ICD-10-CM code for the principal diagnosis for the encounter.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
REIMBURSEMENT CONSIDERATIONS

Coverage for ARISTADA INITIO and/or ARISTADA when administered in the hospital outpatient, psychiatric facility-partial hospitalization, or partial hospitalization in the CMHC setting may vary by payer type. Organizations should use the appropriate code sets based on their structure or services or otherwise consistent with their organizational guidance when filing claims.

**State Medicaid** programs use a variety of reimbursement methods, including fee schedules or other predetermined rates. Drugs administered in the hospital outpatient setting may be reimbursed separately from professional services based on a set rate, such as WAC, AWP, invoice cost, or a percentage of ASP. Actual reimbursement methodologies vary by state, and healthcare professionals should contact the state Medicaid program for more information about coverage for ARISTADA INITIO and/or ARISTADA.

**Medicare** beneficiaries and those who are dual eligible generally have coverage for hospital outpatient services under Part B. Reimbursement is based on the hospital Outpatient Prospective Payment System and payment is based on a payment rate. Coverage and reimbursement may also vary according to facility designation: hospital or partial hospitalization setting. Medicare has specific criteria for what it will cover under Part B as “partial hospitalization” services and recently updated its definition of the criteria CMHCs must meet to qualify as providers of partial hospitalization services (see Medicare criteria on the following page). CMHCs that meet the Medicare criteria may be able to bill Medicare for partial hospitalization through hospital Outpatient Prospective Payment System.

**Commercial** payers may reimburse services and drugs provided in the hospital outpatient and partial hospitalization settings in a variety of ways, including fee schedules based on payer contract, usual and customary charges, a percentage of WAC, AWP, ASP, or other pre-negotiated rates.
Medicare criteria for CMHC to provide partial hospitalization services

A CMHC may receive Medicare payment for partial hospitalization services if:

- It provides outpatient services, including specialized outpatient services for children, elderly individuals, individuals with chronic mental illness, and residents of the community that have been discharged from inpatient treatment at a mental health facility
- It provides 24-hour-a-day emergency care
- It provides day treatment, partial hospitalization, or psychosocial rehabilitation services
- It provides at least 40% of its services to individuals who are not eligible for benefits under Medicare
HOSPITAL INPATIENT

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
HOSPITAL INPATIENT

Trial ARISTADA in the inpatient setting to provide access to treatment for your hospitalized patients.

**Hospital Inpatient Free Trial Program**

<table>
<thead>
<tr>
<th>FREE TRIAL</th>
<th>Order and receive free trial units for your appropriate hospitalized patients with schizophrenia.</th>
</tr>
</thead>
</table>
| ANY DOSE    | • Patients may receive up to 2 free trial units per calendar year of ARISTADA INITIO and/or ARISTADA, subject to quantity limits  
• ARISTADA INITIO will be offered and available to ship with each ARISTADA dose ordered  
  – Medication errors, including substitution and dispensing errors, between ARISTADA INITIO and/or 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 profiles12  
• The Hospital Inpatient Free Trial Program includes all available strengths of ARISTADA |
| REGISTER NOW | To participate, pharmacists of eligible inpatient hospitals can enroll at alkermeshospitalprogram.com to trial patients on ARISTADA free of charge. |

Free trial units provided through this program are for the benefit of patients and cannot be sold, bartered, returned for credit, or billed to the patient, the patient’s insurer, or any government healthcare program, and must also be reported on any cost report or as otherwise required.

There is no requirement for subsequent use of ARISTADA or any Alkermes product for any patient receiving a free trial unit through this program. For full eligibility terms and restrictions, visit aristadacaresupport.com.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
CODING FOR ARISTADA INITIO AND ARISTADA

When submitting claims for a patient's treatment with ARISTADA INITIO and/or ARISTADA, it is important to use codes that accurately reflect the patient's condition, treatment, and other services rendered. Different coding systems are used to describe a patient's medical condition, the drugs administered, and services provided. Submission of claims with inaccurate or incomplete codes may result in delayed or incorrect payment or denial of claims. This section describes the ARISTADA INITIO and/or ARISTADA code sets.

The 837I (Institutional) is the standard format used by institutional providers to transmit claims electronically.53

The 837I and UB-04 also may be suitable for billing various government and some commercial insurers. Please check with Medicaid programs and private payers for specific details and processes.53

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Coding decisions should be made by the physician based on an independent review of the patient's condition.

**Quick Reference Table for UB-04/CMS-1450/837I**

<table>
<thead>
<tr>
<th>Field/category name</th>
<th>ARISTADA INITIO1,44,45,54,59</th>
<th>ARISTADA2,44,45,54,59</th>
<th>837I loop ID, segment/data element13</th>
<th>CMS-1450 (02/12) field number13</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue code</strong></td>
<td></td>
<td></td>
<td>Loop 2400, SV201</td>
<td>Field 42</td>
</tr>
<tr>
<td></td>
<td>• For non-Medicare payers, revenue code 0250 (general pharmacy)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Injection services may be reported with revenue code 0510 (clinic, general service); 0940 (other therapeutic services, general)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Procedures, services, or supplies</strong></td>
<td>675 mg: NDC 65757-0500-03</td>
<td>441 mg: NDC 65757-0401-03</td>
<td>Loop 2400/ SV101</td>
<td>Field 43</td>
</tr>
<tr>
<td><strong>NDC</strong></td>
<td>662 mg: NDC 65757-0402-03</td>
<td>882 mg: NDC 65757-0403-03</td>
<td>1064 mg: NDC 65757-0404-03</td>
<td></td>
</tr>
<tr>
<td><strong>ICD-10-PCS</strong></td>
<td>3E023GC</td>
<td>Introduction of other therapeutic substance into muscle, percutaneous approach</td>
<td>Loop 2300/ HI/BBR</td>
<td>Field 74</td>
</tr>
<tr>
<td><strong>HCPCS</strong></td>
<td>J1943 Injection, aripiprazole lauroxil, (ARISTADA INITIO), 1 mg</td>
<td>J1944 Injection, aripiprazole lauroxil, (ARISTADA), 1 mg</td>
<td>Loop 2400/ SV2/HC</td>
<td>Field 44</td>
</tr>
<tr>
<td><strong>Units</strong></td>
<td>675 billing units for 675 mg</td>
<td>• 441 billing units for 441 mg</td>
<td>Loop 2400/ SV2</td>
<td>Field 46</td>
</tr>
<tr>
<td></td>
<td>• 662 billing units for 662 mg</td>
<td>• 882 billing units for 882 mg</td>
<td>• 1064 billing units for 1064 mg</td>
<td></td>
</tr>
<tr>
<td><strong>ICD-10-CM</strong></td>
<td>Input appropriate diagnosis code</td>
<td></td>
<td>Loop 2300/ HI01-2 (HI01-1=BK)</td>
<td>Field 67 and 67A-67Q</td>
</tr>
<tr>
<td></td>
<td>F20.0 Paranoid schizophrenia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>F20.1 Disorganized schizophrenia</td>
<td></td>
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<tr>
<td></td>
<td>F20.2 Catatonic schizophrenia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>F20.3 Undifferentiated schizophrenia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>F20.5 Residual schizophrenia</td>
<td></td>
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<tr>
<td></td>
<td>F20.89 Other schizophrenia</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>F20.9 Unspecified schizophrenia</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>


Other codes may be appropriate for billing for ARISTADA INITIO and/or ARISTADA. Depending on the site of care, providers may need to use a variety of codes to bill for other types of services provided to a patient. Rules regarding coverage and payment for services vary according to payer and should be verified before submitting claims.

**Note:** Payer policy may vary on requirements for billing two separate drug injections on the same date. Please review individual payer policy.

Please see **Important Safety Information** on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
SAMPLE CLAIM FORMS

Checklist for submitting electronic or paper inpatient claims for ARISTADA INITIO and/or ARISTADA

Prior to treatment or submitting a claim, ensure that all payer requirements for coverage are met, such as:

**Letter of medical necessity, if needed**
- ✔ Include documentation, as needed, if a step edit exists
- ✔ Attach prescribing information

**Claim form completion and submission**
- ✔ Use the claim form and preferred format (eg, electronic or paper) designated by the payer
- ✔ Identify correct dates of service
- ✔ Provide correct and accurate coding
- ✔ Correctly specify number of billing units
- ✔ Provide the full documentation required by the payer including healthcare professional order, if requested
- ✔ Ensure documentation includes a valid and legible healthcare professional signature or acceptable e-signature
- ✔ Submit claim within the payer’s designated claim filing time frame

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
ARISTADA INITIO and ARISTADA **Same Day** Administration

**Hospital Inpatient**

Recording Drug Administration

- ARISTADA INITIO and ARISTADA may be administered on the same day.
- This billing form is an example of when drug administration happens on the same date. ARISTADA INITIO 675 mg and ARISTADA 662 mg is administered on MMDDYY.

### Field 42-43: Enter the appropriate revenue code and description corresponding to the HCPCS code in field 44.
- **0250** for ARISTADA and ARISTADA INITIO
- **0940** for IM injection administered in the hospital inpatient setting

**Note:** Other revenue codes may apply.

### Field 44: Enter appropriate CPT/HCPCS codes and modifiers.
- **Drug:** J1943 for ARISTADA INITIO; J1944 for ARISTADA
- **Administration:** 96372 for IM injection

### Field 46: Enter the appropriate number of units for each line item. When billing ARISTADA INITIO and/or ARISTADA, 1 billing unit is equal to 1 mg.
- ARISTADA
  - 441 billing units for 441 mg
  - 662 billing units for 662 mg
  - 882 billing units for 882 mg
  - 1064 billing units for 1064 mg
- ARISTADA INITIO
  - 675 billing units for 675 mg

**Note:** Enter 2 units for ARISTADA INITIO and/or ARISTADA, 1 unit. When billing ARISTADA INITIO and/or ARISTADA, 1 billing unit is equal to 1 mg.

### Field 67 and 67A-67Q: Enter the appropriate ICD-10-CM diagnosis code for the principal diagnosis for the encounter.
- (* = specific 4th-5th digit required; final code depends on medical record documentation)

**Note:** Other diagnoses codes may apply.

### Field 74: Enter principal ICD-10-PCS code.
- 3E023GC for Introduction of other therapeutic substance into muscle, percutaneous approach

This information is for example purposes and payer coding and billing requirements may vary. Please refer to payer guidance for specific claim form submission or specific coding use.

Please see **Important Safety Information** on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
ARISTADA INITIO and ARISTADA Different Day Administration

Hospital Inpatient

Recording Drug Administration

- The first ARISTADA injection may be administered up to 10 days after ARISTADA INITIO.
- This billing form is an example of when drug administration happens on different dates within an inpatient stay. ARISTADA INITIO 675 mg is administered on 11/01/21, while ARISTADA 662 mg is administered on 11/08/21

Field 42-43: Enter the appropriate revenue code and description corresponding to the HCPCS code in field 44
- 0250 for ARISTADA and ARISTADA INITIO
- 0940 for IM injection administered in the hospital inpatient setting

Note: Other revenue codes may apply

Field 44: Enter appropriate CPT/HCPCS codes and modifiers
- Drug: J1943 for ARISTADA INITIO; J1944 for ARISTADA
- Administration: 96372 for IM injection

Field 46: Enter the appropriate number of units for each line item. When billing ARISTADA INITIO and/or ARISTADA, 1 billing unit is equal to 1 mg

- 0940 for ARISTADA INITIO

Field 67 and 67A-67Q: Enter the appropriate ICD-10-CM diagnosis code for the principal diagnosis for the encounter
(* = specific 4th–5th digit required; final code depends on medical record documentation)

Field 74: Enter principal ICD-10-PCS code
- 3E023GC for Introduction of other therapeutic substance into muscle, percutaneous approach

This information is for example purposes and payer coding and billing requirements may vary. Please refer to payer guidance for specific claim form submission or specific coding use.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
ARISTADA Only Administration
Hospital Inpatient

Recording Drug Administration

- Following is an example of billing forms when ARISTADA 662 mg is administered only.

| Field 42-43: | Enter the appropriate revenue code and description corresponding to the HCPCS code in field 44
| - 0250 for ARISTADA
| - 0940 for IM injection administered in the hospital inpatient setting

Note: Other revenue codes may apply

Field 44: Enter appropriate CPT/HCPCS codes and modifiers
- Drug: J1944 for ARISTADA
- Administration: 96372 for IM injection

Field 46: Enter the appropriate number of units for each line item. When billing ARISTADA, 1 billing unit is equal to 1 mg ARISTADA
- 441 billing units for 441 mg
- 662 billing units for 662 mg
- 882 billing units for 882 mg
- 1064 billing units for 1064 mg

Field 67 and 67A-67Q: Enter the appropriate ICD-10-CM diagnosis code for the principal diagnosis for the encounter
(* = specific 4th-5th digit required; final code depends on medical record documentation)

Field 74: Enter principal ICD-10-PCS code
- 3E023GC for Introduction of other therapeutic substance into muscle, percutaneous approach

This information is for example purposes and payer coding and billing requirements may vary. Please refer to payer guidance for specific claim form submission or specific coding use.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
COMPLETING THE CMS-1450 CLAIM FORM

1. **Field 42** - Enter the appropriate revenue code. ARISTADA may be reported with 0250 (pharmacy, general) and the administration may be reported with 0940 (other therapeutic services, general). Other revenue codes may apply, check individual payer requirements.

2. **Field 43** - Enter the description of corresponding HCPCS code listed in field 44 (field 43)
   - a. Enter the NDC in the unshaded area in field 43
      - i. Qualifier N4 should be added before the 11-digit NDC
         1. ARISTADA INITIO N465757050003
         2. ARISTADA N465757040203 for a 662 mg injection
   - b. Check individual payer requirements for additional NDC reporting requirements (i.e., unit of measure and quantity of drug).

3. **Field 44** - Enter the appropriate CPT/HCPCS codes. ARISTADA INITIO may be reported with HCPCS code J1943, ARISTADA may be reported with HCPCS code J1944, administration may be reported with CPT code 96372.

4. **Field 46** - Enter the appropriate billing units for each line item. When billing ARISTADA INITIO and ARISTADA, 1 billing unit is equal to 1 mg
   - a. ARISTADA
      - i. 441 billing units for 441 mg
      - ii. 662 billing units for 662 mg
      - iii. 882 billing units for 882 mg
      - iv. 1064 billing units for 1064 mg
   - b. ARISTADA INITIO
      - i. 675 billing units for 675 mg

5. **Field 67** - Enter the appropriate ICD-10-CM code for the principal diagnosis for the encounter.

6. **Field 74** - Enter the appropriate ICD-10-PCS procedure code.

Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Coverage for ARISTADA INITIO and/or ARISTADA administered in the hospital inpatient setting varies by type of payer but is similar for both acute care hospitals and psychiatric facilities. There are several primary payment methodologies used in the hospital inpatient setting:

- **Diagnosis-Related Groups (DRGs)**
  - Medicare Severity DRGs (MS-DRGs)
  - All Patient Refined DRGs (APR-DRGs)

- **Per diem rates**

**Medicaid** regulations require that each state pay for inpatient hospital and long-term care services. Medicaid payment for inpatient services provided in general or psychiatric hospitals varies by state agency.

**Medicare** reimburses for most hospital inpatient stays (except for psychiatric hospitals and most inpatient psychiatric units) according to the Inpatient Prospective Payment System based on DRGs. These are determined by the ICD-10 diagnoses and procedure codes entered onto the claims form, which are then grouped to determine the appropriate MS-DRG. Most services and supplies provided during the stay, including medications, are bundled in the MS-DRG reimbursement rate. Hospitals receive one MS-DRG payment per patient inpatient stay and under certain circumstances are also eligible for additional outlier payments.

Medicare reimburses qualified psychiatric hospitals and inpatient psychiatric units in acute care and critical access hospitals on a per diem basis. As with the DRG system, the per diem method does not typically make separate reimbursement for drugs.

**Commercial** payers may cover hospital inpatient treatment with ARISTADA INITIO and/or ARISTADA in several ways. Many payers use a global payment rate that includes most or all services and medications that are usually based on modified MS-DRGs. Other commercial and managed care plans reimburse based on case rates; usual, customary and reasonable charges; discounted charges; or per diem rates. If you are researching coverage for ARISTADA INITIO and/or ARISTADA for a hospital inpatient, contact the patient’s plan to determine if it will reimburse separately for medications provided in the hospital inpatient setting.

Please see **Important Safety Information** on pages 4-7 and full Prescribing Information, including Boxed Warning, for **ARISTADA INITIO** and **ARISTADA**.
REFERENCES

1. ARISTADA INITIO [prescribing information]. Alkermes, Inc; 2022.

2. ARISTADA [prescribing information]. Alkermes, Inc; 2022.


Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
https://www.medicare.gov/coverage/mental-health-care-partial-hospitalization


https://www.medicare.gov/drug-coverage-part-d/how-to-get-prescription-drug-coverage

https://www.healthaffairs.org/do/10.1377/hpb20171008.000172/full/


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Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.


33. Academy of Managed Care Pharmacy. What are prior authorization and the formulary exception process? J Manag Care Pharm. 2005;11(4).


Please see Important Safety Information on pages 4-7 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.


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