ARISTADA INITIO AND ARISTADA REIMBURSEMENT GUIDE

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

IMPORTANT SAFETY INFORMATION FOR ARISTADA INITIO AND ARISTADA

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS
Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ARISTADA INITIO and ARISTADA are not approved for the treatment of patients with dementia-related psychosis.

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

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
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Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
INTRODUCTION

About this guide

The treatment of schizophrenia is complicated and can involve multiple sites of care, provider resources, and different approaches to treatment over time. People living with schizophrenia may have complex health insurance coverage as well, with some having overlapping coverage from different payers, or gaps in coverage from one payer that are met by another.

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

- Healthcare professional offices
- Community Mental Health Centers (CMHCs)
- Partial hospitalization treatment programs
- Hospital outpatient
- Hospital inpatient

Tips for using this guide

The ARISTADA INITIO and ARISTADA Reimbursement Guide is designed to help patients gain access to treatment with ARISTADA INITIO and/or ARISTADA based on the patient’s prescription drug coverage and site of care. Information is organized by payer type and site of care.

For information and tips on how payers cover ARISTADA INITIO and/or ARISTADA treatment, refer to the ARISTADA INITIO and ARISTADA coverage considerations by payer type section of this guide. For detailed information on billing for treatment with ARISTADA INITIO and/or ARISTADA, refer to the Coverage and reimbursement for treatment with ARISTADA INITIO and ARISTADA by site of care section.

This is not a guarantee of payment, coverage, or reimbursement. Alkermes does not provide any advice, recommendation, guarantee, or warranty relating to coverage, reimbursement, or coding for any product or service. Healthcare providers are responsible for determining coverage and reimbursement information and ensuring the accuracy and completeness of claim submissions for their patients. Coding, coverage, and reimbursement vary significantly by payer, patient, and setting of care and are subject to change. Additional information may exist. Actual coverage and reimbursement decisions are made by individual payers. Contact insurer to confirm coverage of ARISTADA and/or ARISTADA INITIO.

IMPORTANT SAFETY INFORMATION, (cont.)

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.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
INTRODUCTION, (CONT.)

Benefit verification tips for ARISTADA INITIO and/or ARISTADA

- Schizophrenia is a severe mental illness. Some states provide category-level protections for medications used to treat severe mental illness, which may encompass unencumbered access to all antipsychotic medications
- Under Medicare Part D, antipsychotics are one of 6 “protected” drug categories where plans must cover “all or virtually all” prescription medications
- Coverage of ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil) can vary. Thoroughly research a patient’s health insurance plan (or plans) and the prescription coverage of ARISTADA INITIO and/or ARISTADA before it is ordered or prescribed

**FIGURE 1: FACTORS AFFECTING COVERAGE FOR ARISTADA INITIO AND/OR ARISTADA**

ARISTADA Care Support can help with the benefit verification process and provide important information regarding access, coverage, claims, prior authorization and appeals for treatment with ARISTADA INITIO and/or ARISTADA.

Contact ARISTADA Care Support at 1-866-ARISTADA (1-866-274-7823).

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Factors affecting coverage

Three main considerations affect coverage and reimbursement for treatment with ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil) (Figure 2). These are:

1. **Type of payer** – Insurance coverage varies by type of payer as well as by site of service, patient condition, and medical history. Medicaid and Medicare are important payers for many people living with schizophrenia and many patients may have coverage under both government insurance programs (e.g., dual eligibility). Some patients may have coverage from private or commercial payers, which includes many of the plans that are available to individuals through the state health insurance marketplaces. Fully understanding the patient’s insurance coverage and benefit structure is a key step in helping to obtain treatment with ARISTADA INITIO and/or ARISTADA.

2. **Benefit category** – Providers can obtain ARISTADA INITIO and/or ARISTADA for their patients in different ways, depending on the patient’s insurance coverage and benefit structure—that is, whether the insurance plan covers the medication under the medical benefit or the pharmacy benefit. In some situations, a payer may cover the medication under either or both benefits. This key information can be obtained during the benefit verification process. It is always important to check both the plan’s medical and pharmacy coverage for ARISTADA INITIO and/or ARISTADA.

3. **Site of service** – Insurance coverage of provider-administered medications varies by site where the service is provided. People living with schizophrenia may rely on several different sites of care, including physician offices, CMHCS, partial hospitalizations, hospital outpatient, or hospital inpatient settings. Over time, the site of care may change, as these individuals move in and out of community-based living. It is essential to coordinate care across sites of service to support continued patient access to medication.

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**FIGURE 2: FACTORS AFFECTING COVERAGE FOR ARISTADA INITIO AND ARISTADA**
**ACCESSING ARISTADA INITIO AND ARISTADA: AN OVERVIEW, (CONT.)**

**Definition of your site may vary by payer: CMHCs**
Understanding how each patient’s insurance company recognizes or classifies a CMHC is an essential step in understanding how treatment with ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil) may be covered and reimbursed. When contacting a payer to verify a patient’s insurance coverage, it is important to identify the proper site of service, and determine how each payer classifies the provider organization. For more information about the Centers for Medicare & Medicaid Services (CMS) definitions for CMHCs, please see the relevant Place of Service section of this guide.

This ARISTADA INITIO and ARISTADA Reimbursement Guide contains information about accessing, coding, and reimbursement for the use of ARISTADA INITIO and/or ARISTADA within each payer channel and site of service.

**Pathways for obtaining ARISTADA INITIO and/or ARISTADA**
A site of care has several options for obtaining ARISTADA INITIO and/or ARISTADA, depending on preferences and payer requirements. It is important to always check with each payer prior to ordering or administering ARISTADA INITIO and/or ARISTADA to verify the policies applicable to the patient.

1. **Order ARISTADA INITIO and/or ARISTADA and submit claim (buy and bill)**
This acquisition method allows a site of care the ability to purchase 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 of ARISTADA INITIO and/or ARISTADA 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/or delivery of ARISTADA INITIO and/or ARISTADA to the site for the identified patient.

3. **Retail pharmacy**
In certain circumstances, retail pharmacies may be able to deliver ARISTADA INITIO and/or ARISTADA to a site of care for administration.

**Contact ARISTADA Care Support at 1-866-ARISTADA (1-866-274-7823) for support and assistance with benefit verification, prior authorization (PA), ordering, and patient access for ARISTADA INITIO and/or ARISTADA.**

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
ACCESSING ARISTADA INITIO AND ARISTADA: AN OVERVIEW, (CONT.)

ARISTADA Care Support
ARISTADA Care Support provides a comprehensive suite of services to help make ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil) therapy more accessible for your patients.

Accessing Treatment
With enrollment, we can help verify patients’ coverage and offer assistance. Additional programs are available to help patients pay for their ARISTADA INITIO starter dose and/or ARISTADA treatment when needed.
- Access support
- Prior authorization and appeals assistance
- Co-pay Savings Program
- Patient Assistance Program

Supporting Continuity of Care
ARISTADA Care Support can provide transition of care support for patients when they are moving from inpatient to outpatient settings. Ongoing appointment reminders are also available once the patient has transitioned to outpatient care.
- Transition of Care Support Program
  - Appointment scheduling and reminders
  - ARISTADA Provider Network
- Live representative – Call 1-866-ARISTADA (1-866-274-7823) to receive general coverage information, including prior authorization requirements. We can also execute a full benefit investigation upon receiving a patient’s enrollment with ARISTADA Care Support. We’ll follow up with patient-specific research, including plan-specific prior authorization requirements, usually within 24 hours.

Learn more at aristadacaresupport.com, or call us at 1-866-ARISTADA (1-866-274-7823) Monday through Friday, 9 AM to 8 PM EST

IMPORTANT SAFETY INFORMATION, (cont.)
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.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
ARISTADA INITIO and/or ARISTADA coverage considerations by payer type

A patient’s coverage for treatment with ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil) will vary based on the type of insurance they have and each payer’s specific policies regarding coverage and reimbursement for treatment with long-acting injectable atypical antipsychotic medications.

There are two major types of payers that provide coverage for persons living with schizophrenia: public insurance programs funded by state or federal governments (e.g., Medicaid and Medicare), and private (or commercial) insurance, which includes plans available to individuals through the health insurance marketplaces (Figure 3).

This is not a guarantee of payment, coverage, or reimbursement. Alkermes does not provide any advice, recommendation, guarantee, or warranty relating to coverage, reimbursement, or coding for any product or service. Healthcare providers are responsible for determining coverage and reimbursement information and ensuring the accuracy and completeness of claim submissions for their patients. Coding, coverage, and reimbursement vary significantly by payer, patient, and setting of care and are subject to change. Additional information may exist. Actual coverage and reimbursement decisions are made by individual payers. Contact insurer to confirm coverage of ARISTADA and/or ARISTADA INITIO.

IMPORTANT SAFETY INFORMATION, (cont.)

Neuroleptic Malignant Syndrome (NMS): A potentially fatal symptom complex may occur with administration of antipsychotic drugs, including ARISTADA INITIO and ARISTADA. Clinical manifestations of NMS include hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). (continued on page 12)
MEDICAID

Medicaid provides coverage for many people living with schizophrenia. It is jointly administered by each state and CMS, operated by the federal government, and covers various groups of individuals, including people with disabilities and individuals who have little income. Some states have extended coverage to nondisabled adults with limited incomes and Medicaid is expected to continue to grow as more states opt in to expand their programs under the Affordable Care Act (ACA).

Federal law requires that states cover certain benefits for Medicaid beneficiaries, but other benefits are determined at the state level. Prescription drug coverage, home and community-based services are some of the optional Medicaid benefits that are determined on a state-by-state basis.

Medicaid 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 ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil). These may include policies such as dose limitations, prior authorization (PA), step edits, or use of an in-network pharmacy. Other states may protect treatment for schizophrenia as a severe mental illness to ensure that patients have access to care and treatment options, including treatment with drugs like ARISTADA INITIO and/or ARISTADA.

Contact the state Medicaid office to determine what type of benefit coverage the patient has and how this may affect coverage for treatment with ARISTADA INITIO and/or ARISTADA.

MANAGED MEDICAID

Depending on where a practice or place of service is located, more than 50% of Medicaid patients may receive coverage through a Managed Medicaid plan that is administered by a commercial payer, such as UnitedHealth Group, Anthem®, or Molina. States continue to expand their participation in Managed Medicaid programs.

Patients who are enrolled in Managed Medicaid plans may have different coverage for ARISTADA INITIO and/or ARISTADA than patients covered under a state Fee-for-Service (FFS) Medicaid program. 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 his or her 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.

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MEDICAID, (CONT.)

MEDICAID FEE-FOR-SERVICE (FFS)
Until the migration toward Managed Medicaid, states purchased healthcare services for Medicaid beneficiaries largely on a Fee-For-Service (FFS) basis. Under state Medicaid FFS plans, providers are paid for services based on a set fee schedule, usually a fixed percentage of the Medicare rate. Some states continue to operate on a FFS basis or offer both Managed Medicaid and FFS options.

Although states are not required to include prescription drug coverage in their state Medicaid plan, currently all 50 states cover prescription drugs. Each state determines what medications will be included in the Medicaid formulary and whether the state will maintain authority over the formulary if it contracts with payers to administer and manage care for its Medicaid beneficiaries. Medicaid plans may have different names for their formulary, such as preferred drug list (PDL), contracted drug list (CDL), prescription injectable drug list (PIDL), or other state-determined name. Long-acting injectable antipsychotics are commonly included in these formularies. Some states provide a category-level protection and do not review antipsychotic agents. In these cases, new agents can be automatically added to the state’s drug list, or in other cases, covered without a formal addition. However, since there is considerable variation between states, it is important to understand the state’s coverage of ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil).

ARISTADA INITIO AND/OR ARISTADA MAY BE COVERED AS EITHER A MEDICAL OR PHARMACY BENEFIT UNDER MEDICAID
When ARISTADA INITIO and/or ARISTADA are covered by a Medicaid plan as a pharmacy benefit, the healthcare professional writes a prescription and submits it to the pharmacy (which can be specialty, retail, or mail order). The pharmacy then ships the medication to the healthcare professional’s site of service. In some cases, the Medicaid plan may specify that the prescription be filled by a specific pharmacy or pharmacy provider, such as a Specialty Pharmacy Provider (SPP). In these cases, the pharmacy provider is responsible for submitting the claim for ARISTADA INITIO and/or ARISTADA and the healthcare professional bills for administering the injection and other professional services.

If ARISTADA INITIO and/or ARISTADA are covered by a Medicaid plan under the medical benefit, healthcare professional offices and CMHCs may be able to purchase and administer ARISTADA INITIO and/or ARISTADA in the healthcare professional-office setting. This process, also called “buy-and-bill,” may allow the healthcare professional or organization to use their National Provider Identifier (NPI) to bill for the different components of treatment, such as the cost of purchasing a medication, the injection/administration, and other services. The reimbursement methodology can vary based on each state’s reimbursement methodology for buy and bill, so it’s important to contact the state Medicaid program to verify the reimbursement amount for ARISTADA INITIO and/or ARISTADA.

MEDICAID PATIENT FINANCIAL RESPONSIBILITY/COST-SHARING FOR TREATMENT WITH ARISTADA INITIO AND/OR ARISTADA
Medicaid cost-sharing requirements for treatment with long-acting injectable antipsychotics vary by state, by site of care, and the patient’s coverage. In general, Medicaid plans offer patients living with schizophrenia access to antipsychotic medications at a nominal cost. Many states waive co-pay policies for drugs used to treat severe mental illness. To encourage the use of lower-cost drugs, states may establish different co-pays for generic drugs and brand-name drugs, or for drugs included on a preferred drug list. For people with incomes at or below the 100% of the federal poverty level (FPL), co-pays will generally be lower for nonpreferred drugs. Contact the state Medicaid plan, search its website for information, or contact ARISTADA Care Support at 1-866-ARISTADA (1-866-274-7823) for information about co-pay for Medicaid beneficiaries.
MANAGED MEDICAID AND MEDICAID APPEALS

If a Managed Medicaid or Medicaid payer denies a prescription, PA, or claim for ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil), the plan is required to include information in the denial notice about how to appeal, with details about who to contact for more information. For questions about denial of a PA or claim, the first step is to contact the state Medicaid plan, or the Managed Medicaid plan.

The specific processes, levels, and deadlines or time limits in state Medicaid appeals processes vary from state to state. However, the federal rules governing Medicaid require that plans offer opportunities to request an appeal, or “fair hearing” as the process is called by many programs, in specific situations. These required opportunities for a fair hearing include:

- A patient’s claim for services is denied or not acted on with reasonable promptness
- The patient or healthcare professional believes that the plan has acted erroneously in delaying the delivery of, terminating, suspending, or reducing Medicaid covered services on the grounds of medical necessity
- A managed care plan enrollee wishes to challenge the denial of coverage or payment for services

For Medicaid FFS, the appeals process generally includes the following steps and deadlines:

- The state agency notifies the beneficiary of a claim denial or intended action
- The beneficiary (or representative) requests a hearing within a reasonable time established by the state agency (at least 20 days and not more than 90 days)
- The state has the option to provide a local-level evidentiary hearing
- If the hearing decision is adverse to the beneficiary, a state fair hearing can be requested within 15 days of the date the decision was mailed
- If the state fair-hearing decision is adverse, the beneficiary may seek judicial review in the state court, as available. All states make some review available as a matter of state law

Patients enrolled in Managed Medicaid plans may have access to supplementary appeals procedures. The federal Medicaid Act requires Managed Care Organizations (MCOs) to establish internal appeal procedures that allow enrollees to challenge the denial or coverage or payment for medical services. These internal appeal procedures may be faster than a state fair hearing, or they may delay the time in which a patient has access to a fair hearing.

In general, the MCO appeals process begins with a written Notice of Action and federal law requires that specific information be included in these notices of action. It is important to follow state regulations and designated processes and deadlines to ensure the patients’ rights are upheld during a Medicaid appeal.

### Required contents of MCO notices of action

- Explanation of the action
- Reason for the action
- Right to file MCO appeal
- Right to request state fair hearing (if exhaustion of MCO appeal process not required first)
- Procedures for exercising MCO appeal rights
- When expedited resolution is available and how to request it
- Right to continue services pending appeal, how to request it and when an enrollee is liable to repay costs
MEDICAID, (CONT.)

ADDITIONAL PATHWAYS TO MEDICATION ACCESS FOR PATIENTS WHO ARE MEDICAID ELIGIBLE

Many people with low incomes and disabilities are eligible for Medicaid but may not be enrolled. It is not unusual for people living with schizophrenia to move in and out of insurance coverage during different periods of their lives. This may include eligibility for different types of government-sponsored health coverage programs, such as Medicaid, Medicare, or both.

If a patient was recently hospitalized or moved into a community-based living situation from another type of care site, ask whether he or she has Medicaid. If the patient is not enrolled (or does not know if he or she is enrolled), the patient can apply through the state Medicaid offices. Once the application process is completed, the patient can be enrolled in the appropriate level or type of Medicaid program that meets his or her individual needs, history, and current situation, if he or she qualifies.

For more information about different types of Medicaid eligibility and some of the programs that may be available to help patients obtain the coverage and benefits they need, please refer to the Dual eligibility: Medicare and Medicaid coverage section of this document. Contact ARISTADA Care Support 1-866-ARISTADA (1-866-274-7823) for more information about programs that can help patients access treatment with ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil).

ARISTADA Care Support can help determine coverage for patients with Medicaid. Call 1-866-ARISTADA (1-866-274-7823) for more information.

IMPORTANT SAFETY INFORMATION, (cont.)

Neuroleptic Malignant Syndrome (NMS), (cont.): 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.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
MEDICARE

Medicare, the healthcare benefit plan administered by the federal government, covers individuals 65 years of age and older, certain disabled individuals, and individuals diagnosed with end stage renal disease. For people living with schizophrenia who are eligible, Medicare is an important payer for medications such as ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil).

As a patient with schizophrenia who is Medicare-eligible moves through different sites of care, coverage for the cost of their prescriptions and medical care will change, based on the Medicare four-part benefit design. Services covered in each of the four parts of Medicare are summarized in Figure 4.

FIGURE 4: MEDICARE AT A GLANCE

Medicare Part A (Hospital Insurance)
Includes inpatient hospital care, skilled nursing facility, home health care, and hospice care

Medicare Part B (Medical Insurance)
Includes medically necessary outpatient hospital services, doctor visits, home health care, laboratory services, durable medical equipment, preventive services, and limited provider-administered drugs, including some oral drugs

Medicare Advantage (MA)
Combines Part A and Part B through a managed care
OR
Medicare Advantage-Prescription Drug (MA-PD)
Combines Part A and Part B, along with Part D, through a managed care plan

Medicare Part D (Outpatient Prescription Drug Coverage)

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
MEDICARE, (CONT.)

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

**Medicare Part B (Medical Insurance):** Outpatient hospital care and outpatient mental healthcare are covered under Medicare Part B. Part B also may cover partial hospitalization by a CMHC, 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.

**Medicare Advantage:** Most people sign up for original Medicare, which consists of Part A and Part B. However, a growing number of individuals are signing up for Medicare Advantage plans, which combine Part A and Part B with additional benefits, such as prescription drug coverage. Medicare Advantage plans are managed by private/commercial insurance companies under contract with the CMS. Patients in most areas can choose from a wide variety of different plans and benefit options. Prescription drug plans that are offered as part of a Medicare Advantage plan are called Medicare Advantage-Prescription Drug (MA-PD) plans, which may cover long-acting injectable antipsychotics under Part B; others may cover them under Part D. Some Medicare Advantage plans include special options for patients who may be institutionalized, are eligible for both Medicare and Medicaid, or who have chronic conditions; these are known as Medicare Advantage Special Needs Plans (SNPs).

**Medicare Part D (Outpatient Prescription Drugs):** Medicare Part D was created in 2006 to provide beneficiaries with coverage for outpatient prescription medications. It 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 and individuals can choose a Prescription Drug Plan (PDP) that best meets their needs.

Some people with low incomes or disabilities may qualify for automatic enrollment in the Part D Low-Income Subsidy (LIS) program, also known as Medicare Extra Help. For more information, please see [Dual eligibility: Medicare and Medicaid coverage](#).

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**MEDICARE PART D PROTECTED DRUG CLASSES**

CMS requires that all Part D plan formularies include “all or substantially all” drugs in 6 categories:

- Antipsychotic
- Anticonvulsant
- Antidepressant
- Antineoplastic
- Antiretroviral
- Immunosuppressant (for prophylaxis of organ transplant rejection)

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MEDICARE, (CONT.)

MEDICARE PATIENT COST-SHARING/FINANCIAL RESPONSIBILITY FOR ARISTADA INITIO AND/OR ARISTADA

Medicare coverage for ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil) will vary depending on site of care, benefit coverage and the patient’s individual insurance plan. This section outlines some of the policies that generally guide patient cost-sharing or out-of-pocket financial responsibility for treatment with ARISTADA INITIO and/or ARISTADA.

Medicare Part A

Medicare Part A covers inpatient hospital care, whether in an acute care facility or a psychiatric facility. Most beneficiaries do not pay a premium for Medicare Part A. Instead, they are responsible for a deductible and a daily coinsurance rate that begins after the 60th day of each benefit period. Coverage of drugs like ARISTADA INITIO and/or ARISTADA, when administered under a site of care covered by Part A, are usually included with the Part A cost of service and are not separately billable. Instead, drugs are often included within the Medicare Severity Diagnosis Related Group (MS-DRG) payment, which is used for the Medicare Inpatient Prospective Payment System (IPPS) for acute care inpatient hospital stays. Drugs are also generally bundled into the per diem payment made to inpatient psychiatric facilities and psychiatric departments of acute care hospitals.

Many people with original Medicare purchase supplemental or secondary insurance to cover their out-of-pocket obligations. People who are dual eligible for Medicare and Medicaid and qualify for Low-Income Subsidy (LIS) may have lower or no coinsurance (refer to the Dual eligibility: Medicare and Medicaid coverage section for more information).

For people who are not dual eligible, there is a defined inpatient deductible for Medicare Part A per benefit period. The Part A benefit period usually begins the day a patient is admitted to a hospital as an inpatient and ends when the patient hasn’t received any inpatient care for 60 days in a row. There may be more than one benefit period in a calendar year and the patient pays the inpatient hospital deductible and coinsurance for each benefit period. Cost-sharing obligations for inpatient hospitalizations can be found at [https://www.medicare.gov/pubs/pdf/10050-Medicare-and-You.pdf](https://www.medicare.gov/pubs/pdf/10050-Medicare-and-You.pdf). There is a lifetime limit of 190 days of covered inpatient care in a psychiatric hospital; this limit does not apply to mental health treatment provided in a general hospital.

IMPORTANT SAFETY INFORMATION, (cont.)

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.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Medicare Part B

Medicare Part B covers services and supplies that are deemed medically necessary to treat a health condition. This includes outpatient and physician office visits. For patients who are not dual eligible, most beneficiaries will pay a monthly premium along with an annual deductible. Costs are subject to change each benefit year. Medicare pays 80% of allowable costs, while beneficiaries are responsible for a 20% coinsurance for most professional services and drugs. When services are provided in a hospital outpatient setting, the beneficiary coinsurance for separately covered drugs is 20% of the allowable. The coinsurance for other items and services provided by the hospital is 20% of the amount allowed by Medicare, and in some cases additional coinsurance may apply. This is in addition to the 20% coinsurance that applies to professional services rendered in the hospital outpatient setting.

If a patient is covered for treatment with ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil) under Medicare Part B, it is important to determine whether the patient has supplemental coverage that will help pay for his or her coinsurance.

Medicare Advantage

Medicare Advantage (MA) plans provide both Medicare Part A and Medicare Part B benefits and in some cases, outpatient prescription drug (Part D) benefits as well. Medicare Advantage-Prescription Drug (MA-PD) plans include the Medicare Part D benefit described in the Part D section on the following page.

Premiums, deductibles, co-pays, and coinsurance vary from plan to plan. There is no supplemental coverage associated with these plans. MA and MA-PD plans should be contacted to determine each patient’s specific financial obligations.

IMPORTANT SAFETY INFORMATION, (cont.)

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.
Medicare Part D

Medicare Part D PDPs and MA-PDs vary in their coverage of long-acting injectable antipsychotic medications. A plan may cover ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA* (aripiprazole lauroxil) under Part D without restriction or require a Prior Authorization. The patient cost of prescription drugs, including ARISTADA INITIO and/or ARISTADA, can vary significantly by plan, medication and even pharmacy. If not eligible for the Low-Income Subsidy, patients may be responsible for paying a monthly premium, deductible, co-pay, or coinsurance, depending on the plan.7

There are 3 different levels of beneficiaries within Part D11:

- **Standard beneficiaries** – Beneficiaries are not eligible for the Medicare Low-Income Subsidy (LIS), but may be eligible for a senior State Pharmaceutical Assistance Program (SPAP) based on income, resource levels, and other state criteria.
  
The Part D cost structure can change annually. The standard Medicare Part D benefit has an annual deductible and an initial coverage limit.11 After reaching the initial coverage limit, beneficiaries are responsible for a percentage of the cost of prescription medications until they reach the out-of-pocket threshold. After reaching the out-of-pocket threshold, beneficiaries are responsible for a cost-share after the out-of-pocket threshold is reached.

- **Dual eligibility** – Individuals with dual eligibility for Medicare and Medicaid, also known as full subsidy-Full Benefit Dual Eligibles (FBDEs), are automatically enrolled in the Part D LIS and are responsible for a modest co-pay.

- **Other Low-Income Subsidy beneficiaries** – These beneficiaries have incomes less than 150% of the Federal Poverty Level. They may be eligible to receive partial assistance from Medicaid in paying for their Part D out-of-pocket expenses.

For more information please refer to the [Dual eligibility: Medicare and Medicaid coverage](#) section of this guide.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Medicare appeals

CMS has a defined process for appeals of both original Medicare, Medicare Advantage, and Part D coverage decisions. Both follow a similar five-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.

ORIGINAL MEDICARE AND MEDICARE ADVANTAGE APPEALS

When ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil) are covered under the Medicare Part B medical benefit, the process for appealing a denial of coverage is similar to the Part D appeals process described below. It involves 5 sequential levels of appeals, from a Request for Redetermination from the plan to a hearing or review by an appeals council or in a Federal District Court. For more information about the Medicare Part B appeals process, consult the Medicare Claims Processing Manual, Chapter 4 – Part B Hospital. This is available for download at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf

Patients with coverage through Medicare Advantage plans follow a similar process, with established procedures for advancing to the next level of appeal defined in writing.

PART D DRUG COVERAGE APPEALS

CMS has defined a five-step process for prescription drug coverage appeals, with specific deadlines and procedures for each level. The levels of appeal range from a coverage redetermination, requesting that a plan reevaluate an initial denial, to the highest level of judicial review in a Federal District Court. The Medicare Part D Prescription Drug Coverage Determination and Appeals Process in Figure 5 summarizes the coverage determination and appeals process, and the key time limits and dollar amount criteria associated with each level of appeal.

Plans are required to accept any written request for a redetermination of coverage from patients, appointed representatives, the patient’s healthcare professional, or other prescriber. A written request to appeal should include:

- The patient’s name, address, Medicare number and/or plan member identification number
- The name of the drug submitted for the appeal
- Stated reason from initial denial of claim, date the denial was issued, and a copy of the denial
- The reasons for the appeal; consider including information similar to that outlined in the sample Letter of Medical Necessity or Appeals Letter
- If the healthcare professional is acting as the patient’s appointed representative in the appeal process, include proof of representation
- Include any other information that may help support the appeal, such as medical records, patient history, or recent chart notes


Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
### FIGURE 5: MEDICARE PART D PRESCRIPTION DRUG COVERAGE DETERMINATION* AND APPEALS PROCESS†

<table>
<thead>
<tr>
<th>Coverage Determination/Appeals Process</th>
<th>Coverage Determination</th>
<th>First Appeal Level</th>
<th>Second Appeal Level</th>
<th>Third Appeal Level</th>
<th>Fourth Appeal Level</th>
<th>Judicial Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>STANDARD PROCESS</td>
<td>72-hour time limit†</td>
<td>60 days to file</td>
<td>60 days to file</td>
<td>60 days to file</td>
<td>60 days to file</td>
<td></td>
</tr>
<tr>
<td>EXPEDITED PROCESS</td>
<td>24-hour time limit†</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PDP/MA-PD</td>
<td>Standard redetermination 7-day time limit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Part D IRE</td>
<td>Standard redetermination 7-day time limit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Office of Medicare Hearings and Appeals</td>
<td>ALJ Hearing Standard decision AIC 90-day time limit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Office of Medicare Hearings and Appeals</td>
<td>ALJ Hearing Expedited decision AIC 10-day time limit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare Appeals Court</td>
<td>Standard decision 90-day time limit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare Appeals Court</td>
<td>Expedited decision 10-day time limit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Federal District Court</td>
<td>AIC‡</td>
<td>60 days to file</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Federal District Court</td>
<td>AIC‡</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviations:**
- AIC = Amount In Controversy
- ALJ = Administrative Law Judge
- IRE = Independent Review Entity
- MA-PD = Medicare Advantage plan that offers Part D benefits
- PDP = Prescription Drug Plan

* A request for a coverage determination includes a request for a tiering exception or a formulary exception. A request for coverage determination may be filed by the Medicare enrollee (patient), by an appointed representative, or by the enrollee’s healthcare provider or other prescriber.

† The adjudication time frames generally begin when the request is received by the plan sponsor. However, if the request involves a formulary exception request, the adjudication time frame begins when the plan sponsor receives the physician’s supporting statement.

‡ The AIC requirement for an ALJ hearing and Federal District Court appeal is adjusted annually in accordance with the medical care component of the consumer price index. For a current price index, visit: [https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/index.html](https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/index.html).

MAXIMUS Federal Services currently manages the Medicare Part D IRE process. All requests from an authorized person must be submitted in writing via mail or fax to MAXIMUS at:

**MAXIMUS Federal Services**
3750 Monroe Avenue, Suite 703
Pittsford, NY 14534-1302
Toll-free fax: 1-866-825-9507

Additional information, including a Request for Reconsideration of Medicare Prescription Denial form, is available on the Medicare Part D appeals website ([http://www.medicarepartdappeals.com](http://www.medicarepartdappeals.com)).
In 2013, there were approximately 10 million low-income elderly and disabled people who were covered under both Medicare and Medicaid. These beneficiaries include many people living with schizophrenia. Medicare is the primary source of health insurance coverage for these individuals. Medicaid supplements Medicare, paying for services not covered by Medicare, such as dental care and long-term care, and by helping to cover Medicare premiums and patient cost-sharing requirements.

The Medicare Part D benefit includes special assistance for Medicare-eligible beneficiaries with limited resources and income. This program, known as the Medicare Low-Income Subsidy (LIS), or Extra Help, can decrease or eliminate any out-of-pocket costs for patients with Medicare Part D.

Three groups of Medicare beneficiaries are automatically enrolled in LIS with full benefits and do not have to apply. These are:

1. Medicare beneficiaries who qualify for full Medicaid benefits (dual eligibility)
2. Beneficiaries enrolled in 1 of 4 Medicare Savings Programs (MSP):
   - Qualified Medicare Beneficiary (QMB) Program - Eligibility for the QMB program automatically qualifies an individual for LIS. The QMB program helps pay for Parts A and B out-of-pocket cost-sharing (premiums, deductibles, coinsurance, and co-pay). CMS automatically enrolls these qualified individuals into PDPs with premiums at or below the regional average (also known as low-income benchmark plans).
   - Specified Low Income Medicare Beneficiary (SLMB) Program - Eligibility for the SLMB program automatically qualifies an individual for LIS. The SLMB program helps pay for Part B premiums only.
   - Qualified Individual (QI) Program - Eligibility for the QI program automatically qualifies an individual for LIS. The QI program helps pay for Part B premiums only.
   - Qualified Disabled and Working Individuals (QDWI) Program - Helps pay Part A premiums for individuals that are disabled and working.
3. Beneficiaries receiving Supplemental Security Income (SSI) from the Social Security Administration. SSI patients receive support from both Medicare and Medicaid.

Again, some people, such as individuals who are dual eligible for Medicaid and Medicare, are automatically enrolled in the LIS program. However, many people who are eligible for LIS are not aware of the program and are not enrolled. People who are not automatically enrolled can apply for LIS.

DUAL ELIGIBILITY: MEDICARE AND MEDICAID COVERAGE

IMPORTANT SAFETY INFORMATION, (cont.)

- **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 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Questions to help determine if a patient is enrolled in or eligible for LIS

Here are some questions to ask patients to help determine whether they are enrolled in LIS:

- **How much do you pay for your prescriptions at the pharmacy?**
  If the response is in the range of $1 to $8, they may be receiving LIS

- **Could you show me all of your insurance cards, including the card you use at the pharmacy for prescriptions?**
  If the patient has both Medicaid and Medicare cards, he or she may be eligible for or already receiving LIS

To help patients learn more about the LIS program, especially if they may be eligible, encourage them to:

- Visit [www.socialsecurity.gov/extrahelp](http://www.socialsecurity.gov/extrahelp)
- Contact the Social Security Administration (SSA) at 1-800-772-1213, where they can speak to a customer service representative for help with the application
- Contact the local State Health Insurance Assistance Program (SHIP). SHIPs are federally funded to provide free, objective assistance to people with Medicare and their families. SHIPs also can help with applications for Extra Help and the Medicare Savings Programs. Call toll-free 1-877-839-2675 or visit the SHIP Technical Assistance Center website: [https://www.shiptacenter.org](https://www.shiptacenter.org)

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ARISTADA Care Support can help determine coverage for patients who may qualify as dual eligible. Call 1-866-ARISTADA (1-866-274-7823) for more information.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
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.

Commercial payers may cover ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil) 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.

**Commercially insured patient cost-sharing/financial responsibility for ARISTADA INITIO and/or ARISTADA**

For patients covered by a commercial insurance plan, cost-sharing will depend on benefit coverage. If the payer covered ARISTADA INITIO and/or ARISTADA under the medical benefit, the patient may only be responsible for the office visit co-pay. Patients also may be responsible for a co-pay or coinsurance for the medication. If ARISTADA INITIO and/or ARISTADA are covered under the pharmacy benefit, the patient may be responsible for the plan’s designated co-pay or coinsurance for the medication.

Complete information about each patient’s cost-sharing obligations for treatment with ARISTADA INITIO and/or ARISTADA should be obtained during the initial benefit verification process.

**Appealing coverage decisions from commercial payers**

For patients with commercial insurance, the process for appealing a coverage decision will be plan specific, although plans are required by law to have a defined appeals process. ARISTADA Care Support is available to assist with coverage, claims, and appeals for treatment with ARISTADA INITIO and/or ARISTADA.

**IMPORTANT SAFETY INFORMATION, (cont.)**

**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.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
CODING FOR ARISTADA INITIO AND ARISTADA: AN OVERVIEW

When submitting claims for a patient’s treatment with ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil), 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 of the ARISTADA INITIO and ARISTADA Reimbursement Guide describes a general approach for providers to coding claims for treatment with ARISTADA INITIO and/or ARISTADA using nationally recognized code sets. Additional details about site-specific variations in coding are discussed in the sites of care and claim forms section of this guide.

This is not a guarantee of payment, coverage, or reimbursement. Alkermes does not provide any advice, recommendation, guarantee, or warranty relating to coverage, reimbursement, or coding for any product or service. Healthcare providers are responsible for determining coverage and reimbursement information and ensuring the accuracy and completeness of claim submissions for their patients. Coding, coverage, and reimbursement vary significantly by payer, patient, and setting of care and are subject to change. Additional information may exist. Actual coverage and reimbursement decisions are made by individual payers. Contact insurer to confirm coverage of ARISTADA and/or ARISTADA INITIO.

IMPORTANT SAFETY INFORMATION, (cont.)
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.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
National Drug Codes (NDCs)

The U.S. Food and Drug Administration (FDA) has established a list of unique, 3-segment numbers that identify all drugs available for commercial distribution in the U.S. called the NDC Directory. Many payers require the use of NDCs on claim submissions for provider-administered drugs. In some cases, the NDC code may be required instead of, or in addition to, the Healthcare Common Procedure Coding System (HCPCS) code.

The NDCs for ARISTADA INITIO® (aripiprazole lauroxil) and ARISTADA® (aripiprazole lauroxil) are as follows:

<table>
<thead>
<tr>
<th>NDC for ARISTADA INITIO (^{18})</th>
<th>NDCs for ARISTADA (^{18})</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dosage Strength</strong></td>
<td><strong>11-digit NDC</strong></td>
</tr>
<tr>
<td>675 mg</td>
<td>65757-0500-03</td>
</tr>
<tr>
<td>441 mg</td>
<td>65757-0401-03</td>
</tr>
<tr>
<td>662 mg</td>
<td>65757-0402-03</td>
</tr>
<tr>
<td>882 mg</td>
<td>65757-0403-03</td>
</tr>
<tr>
<td>1064 mg</td>
<td>65757-0404-03</td>
</tr>
</tbody>
</table>

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Billing for treatment with ARISTADA INITIO and/or ARISTADA: HCPCS codes

HCPCS Level II codes are a standardized coding system for identifying medically related items and services. Prescription drugs are typically reported using product-specific HCPCS codes. These codes are assigned by CMS. Medicare, Medicaid, and most commercial payers require the use of HCPCS codes to report provider-administered drugs and facilitate coverage and payment determinations.

**ARISTADA INITIO® (aripiprazole lauroxil)**
ARISTADA INITIO has not yet been assigned a unique, product-specific HCPCS code. Until this occurs, the following unclassified (miscellaneous) HCPCS codes may be used, depending on the payer and site of care. Unclassified drug codes are used when no existing national code adequately describes the item or service being billed.

<table>
<thead>
<tr>
<th>HCPCS Code19</th>
<th>Description</th>
<th>Settings of Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>J3490</td>
<td>Unclassified drugs</td>
<td>Most payers and care settings</td>
</tr>
<tr>
<td>C9399</td>
<td>Unclassified drugs or biologicals</td>
<td>Outpatient claims billed to Medicare under the Hospital Outpatient Prospective Payment System (OPPS)2</td>
</tr>
</tbody>
</table>

**ARISTADA® (aripiprazole lauroxil)**
ARISTADA received a unique J-code (J1942) on January 1, 2017. The code J1942 may be used when ARISTADA is being billed under the medical benefit.

<table>
<thead>
<tr>
<th>HCPCS Code19</th>
<th>Description</th>
<th>Settings of Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1942</td>
<td>Injection, aripiprazole lauroxil, 1 mg</td>
<td>Most payers and care settings</td>
</tr>
</tbody>
</table>

When submitting a claim to a Medicare Administrative Contractor (MAC), if the MAC requires pricing or other additional information, it will issue an Additional Documentation Request (ADR). Your site should be prepared to provide the additional information requested in a timely manner if an ADR is issued. The ADR may request information such as clinical notes, invoice, or a Letter of Medical Necessity.

**NATIONAL PROVIDER IDENTIFIER (NPI)**

The NPI is a unique 10-digit, intelligence-free numeric identifier used to identify each covered healthcare provider. NPIs must be used for all administrative and financial transactions adopted as a result of the Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification Standard by all covered healthcare providers, health plans, and healthcare clearinghouses.20 It is important to verify that each claim is billed with the performing provider’s assigned NPI.

NPI information is centralized within the National Plan and Provider Enumeration System (NPPES) registry, which enables you to search for a provider’s NPPES information. For more information, visit [https://npiregistry.cms.hhs.gov/](https://npiregistry.cms.hhs.gov/).

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
CODING FOR ARISTADA INITIO
AND ARISTADA: AN OVERVIEW, (CONT.)

American Psychiatric Association, Diagnostic and Statistical Manual (DSM) code set
Mental health professionals use the DSM standard classification of mental disorders in clinical practice and research. These codes are not intended for billing use unless directed by the payer.

DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS, 5TH EDITION (DSM-5): DSM CODE SET
The DSM diagnosis codes for mental health disorders were updated, as of May 2013, in the DSM-5. DSM-5 codes and descriptors should be used as required by the payer.

<table>
<thead>
<tr>
<th>DSM-5 Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>F20.9</td>
<td>Schizophrenia</td>
</tr>
</tbody>
</table>

Diagnostic Codes
The International Classification of Diseases (ICD) code sets are used by most provider offices and CMHCs to report a patient’s specific mental health disorder. Some may also use DSM-5 codes within the patient’s medical record or supporting clinical documentation. Selection of appropriate codes should be supported by the patient’s medical record and the healthcare professional’s clinical judgment. Check with individual payers about any questions about coding documentation for a particular patient.

IMPORTANT SAFETY INFORMATION, (cont.)
Falls: Antipsychotics including ARISTADA INITIO® (aripiprazole lauroxil) and ARISTADA® (aripiprazole lauroxil) 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.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Coding for ARISTADA INITIO and ARISTADA: An Overview, (cont.)

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM)\textsuperscript{22}

Prior to October 1, 2015, payers were required to use the ICD-9-CM diagnosis code set. For services delivered on or after October 1, 2015, all claims for services submitted to payers that use the ICD-CM code set are required to use the ICD-10-CM diagnosis code set, which includes codes such as those listed in the table below.

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>F20.0</td>
<td>Paranoid schizophrenia</td>
</tr>
<tr>
<td>F20.1</td>
<td>Disorganized schizophrenia</td>
</tr>
<tr>
<td>F20.2</td>
<td>Catatonic schizophrenia</td>
</tr>
<tr>
<td>F20.3</td>
<td>Undifferentiated schizophrenia</td>
</tr>
<tr>
<td>F20.5</td>
<td>Residual schizophrenia</td>
</tr>
<tr>
<td>F20.89</td>
<td>Other schizophrenia</td>
</tr>
<tr>
<td>F20.9</td>
<td>Unspecified schizophrenia</td>
</tr>
</tbody>
</table>

CODING FOR ARISTADA INITIO AND ARISTADA: AN OVERVIEW, (CONT.)

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\textsuperscript{®} (aripiprazole lauroxil) and/or ARISTADA\textsuperscript{®} (aripiprazole lauroxil) at the first sign of a clinically significant decline in WBC and in severely neutropenic patients.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
CODING FOR ARISTADA INITIO AND ARISTADA: AN OVERVIEW, (CONT.)

Current Procedural Terminology codes and ICD Procedure Codes: administration intramuscular injection procedure codes in the outpatient and inpatient settings

The use of procedure codes for intramuscular injections can vary by sites of care and payer.

To report the administration of an intramuscular injection of ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil) in the office setting with direct physician or other qualified health professional supervision, it may be appropriate to use the following:


<table>
<thead>
<tr>
<th>Code Set</th>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT® code*</td>
<td>96372</td>
<td>Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular†</td>
</tr>
</tbody>
</table>


* This code is not intended to be reported by the physician in the facility setting.
† ARISTADA INITIO and ARISTADA are administered as IM injections only.

It may also be appropriate for hospitals to use CPT® code 96372 when reporting the facility fee associated with administration of the injection to an outpatient. To report the administration of an intramuscular injection of ARISTADA INITIO and/or ARISTADA in the inpatient hospital setting, payers may require ICD procedure codes. The following ICD procedure codes may be appropriate to report the administration of ARISTADA INITIO and/or ARISTADA in the inpatient hospital setting:

| Procedure Codes: Inpatient Hospital Setting

<table>
<thead>
<tr>
<th>Procedure Code Set</th>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICD-10-PCS</td>
<td>3E023GC</td>
<td>Introduction of other therapeutic substance into muscle, percutaneous approach</td>
</tr>
</tbody>
</table>

Note: If ARISTADA INITIO and/or ARISTADA are injected on the same day in the non-inpatient setting, some payers may require the use of modifiers for the second injection. The first injection is billed without a modifier and the second injection is then billed with a modifier. Typically, modifier 59, “Distinct Procedural Service,” is utilized to convey that two separate drugs were injected on the same date of service. Please note that payer modifiers may be payer specific, please always consult payer guidelines to identify if a modifier is required for multiple injections of separate drugs on the same day and if so, which modifier is required by the payer.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Coding for Aristada Initio and Aristada: An Overview, (Cont.)

Other codes that may be appropriate for billing for Aristada Initio® (aripiprazole lauroxil) and/or Aristada® (aripiprazole lauroxil)

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.

Hospital Outpatient and Ambulatory Payment Classifications

Under the Medicare hospital OPPS, most services are reimbursed based on groups of procedures known as Ambulatory Payment Classifications (APCs). The table below shows the mapping of HCPCS codes to APC that may be appropriate.

Please note, the code for Aristada Initio will not route to an APC.

Aristada

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
<th>Maps to APC</th>
<th>HCPCS Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®23</td>
<td>96372</td>
<td>0436</td>
<td>Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular†</td>
</tr>
<tr>
<td>HCPCS¹⁹</td>
<td>J1942</td>
<td>9470</td>
<td>Injection, aripiprazole lauroxil, 1 mg</td>
</tr>
</tbody>
</table>


* Unclassified Drug C codes are used in the Medicare Outpatient Hospital Setting. The unclassified C code may go directly under the HCPCS codes.
† Aristada is administered as an IM injection only.

Revenue Codes

Hospitals report revenue codes on the UB-04 claim form (or its electronic equivalent) to categorize services by revenue center. Revenue codes can be used in both the inpatient and outpatient hospital setting. Payers use revenue codes to capture hospital cost data. Many payers require that claims include revenue codes for some or all services provided in the hospital setting. Examples of revenue codes that may be relevant for the administration of Aristada Initio and/or Aristada in the hospital setting are shown in the following table.

Aristada Initio and/or Aristada

<table>
<thead>
<tr>
<th>Revenue Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0250</td>
<td>General classification, pharmacy</td>
</tr>
<tr>
<td>0510</td>
<td>Clinic</td>
</tr>
<tr>
<td>0636</td>
<td>Drugs requiring detailed coding</td>
</tr>
</tbody>
</table>

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for Aristada Initio and Aristada.
CPT® codes: Evaluation and Management services (E/M)

A provider office, CMHC, or hospital outpatient clinic may sometimes also bill for an E/M or office visit, in addition to the drug and administration service if there is a separately identifiable reason for the E/M service. Determination of the E/M category (e.g., new vs established patient, hospital inpatient vs hospital outpatient vs hospital observation care) and the level of service to report is up to the discretion of the individual healthcare professional. The separate service should be clearly documented in the patient’s medical record and an appropriate E/M code used. The CPT® Manual, available from the American Medical Association (AMA), can provide guidance to provider offices regarding selection of the correct E/M code for each patient visit. Codes are the same for ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil).

<table>
<thead>
<tr>
<th>Select E/M codes</th>
<th>Description</th>
</tr>
</thead>
</table>
| 99212            | Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components:  
• A problem-focused history  
• A problem-focused examination  
• Straightforward medical decision-making  
Counseling and/or coordination of care with other physicians, other qualified healthcare professionals, or agencies are provided consistent with the nature of the problem(s) and the patient’s family’s needs. Usually, the presenting problem(s) are self-limited or minor. Typically 10 minutes are spent face-to-face with the patient and/or family. |
| 99213            | Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components:  
• An expanded problem-focused history  
• An expanded problem-focused examination  
• Medical decision-making of low complexity  
Counseling and/or coordination of care with other physicians, other qualified healthcare professionals, or agencies are provided consistent with the nature of the problem(s) and the patient’s family’s needs. Usually, the presenting problem(s) are of low to moderate severity. Typically 15 minutes are spent face-to-face with the patient and/or family. |
| 99214            | Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components:  
• A detailed history  
• A detailed examination  
• Medical decision-making of moderate complexity  
Counseling and/or coordination of care with other physicians, other qualified healthcare professionals, or agencies are provided consistent with the nature of the problem(s) and the patient’s family’s needs. Usually, the presenting problem(s) are of moderate to high severity. Typically 25 minutes are spent face-to-face with the patient and/or family. |

E/M CODE MODIFIER

When an E/M service is provided separately from a procedural service, a modifier may be used to identify the separate service provided. The modifier -25 (significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service) may be appropriate for patients receiving other services in addition to treatment with ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil). The healthcare professional’s site should consult with a patient’s payer to identify whether it will cover an office visit on the same day as other healthcare professional services and the appropriate modifier codes to use.

In some circumstances, it may be appropriate to report psychiatric services or procedures in lieu of, or in addition to, E/M services. These services are described by CPT® codes 90791 – 90899. See the current edition of CPT® for descriptions of these codes and guidelines for their use.

ADDITIONAL CPT® CODES: TRANSITIONAL CARE MANAGEMENT (TCM)

There are 2 current CPT® codes for TCM that support transitions of care associated with the management of patients who have recently been discharged from a hospital, skilled nursing facility, or CMHC stay. The codes include services provided to a patient with medical and/or psychosocial problems that necessitate moderate- or high-complexity medical decision-making during a care transition from a hospital setting to the patient’s community setting. Inpatient hospital settings include acute hospital, rehabilitation hospital, long-term acute care hospital, partial hospitalization, observation status while in a hospital, or skilled nursing facility/nursing facility. The community setting includes a patient’s home, domicile, or other assisted living facility.

The codes permit reporting of time spent discussing a patient’s care plan, connecting patients to community services, transitioning a patient from an inpatient setting, and discussions to prevent readmissions.

The codes are the same for ARISTADA INITIO and/or ARISTADA.

<table>
<thead>
<tr>
<th>Select E/M codes</th>
<th>Description</th>
</tr>
</thead>
</table>
| 99495            | Includes communication via direct contact, telephone, or electronic means with the patient and/or caregiver within 2 business days of discharge. Additionally, includes the following requirements:  
• Medical decision-making is at least of a moderate complexity during the service period  
• Face-to-face visit within 14 calendar days of discharge |
| 99496            | Includes communication via direct contact, telephone, or electronic means with the patient and/or caregiver within 2 business days of discharge. Additionally, includes the following requirements:  
• Medical decision-making of high complexity during the service period  
• Face-to-face visit within 7 calendar days of discharge |

Place of Service (POS) codes

POS codes are used on claims to designate where a service is rendered. Different codes may be appropriate for physician offices, non–Medicare-certified CMHCs, and hospital outpatient clinics. The POS codes that may commonly be used for treatment with ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil) are:

- **POS 11** – Office
- **POS 21** – Inpatient Hospital
- **POS 22** – Outpatient Hospital
- **POS 52** – Psychiatric Facility-Partial Hospitalization
- **POS 53** – Community Mental Health Center

<table>
<thead>
<tr>
<th>POS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>POS 11</td>
<td>Office</td>
</tr>
<tr>
<td>POS 14</td>
<td>Group Home</td>
</tr>
<tr>
<td>POS 17</td>
<td>Walk-in Retail Health Clinic</td>
</tr>
<tr>
<td>POS 21</td>
<td>Inpatient Hospital</td>
</tr>
<tr>
<td>POS 22</td>
<td>Outpatient Hospital</td>
</tr>
<tr>
<td>POS 26</td>
<td>Military Treatment Facility</td>
</tr>
</tbody>
</table>

Office
This code applies to healthcare professional offices or other sites that provide services to patients who do not require hospitalization.

Group Home
A residence, with shared living areas, where clients receive supervision and other services such as social and/or behavioral services, custodial service, and minimal services (e.g., medication administration).

Walk-in Retail Health Clinic
A walk-in health clinic, other than an office, urgent care facility, pharmacy, or independent clinic, and not described by any other Place of Service code, that is located within a retail operation and provides, on an ambulatory basis, preventive and primary care services.

Inpatient Hospital
A facility, other than psychiatric, which primarily provides diagnostic, therapeutic, and rehabilitation services. Physicians provide or supervise services to admitted patients for a variety of medical conditions.

Outpatient Hospital
This code applies to outpatient sites of care where the patient is not required to be hospitalized or institutionalized.

Military Treatment Facility
A medical facility operated by one or more of the Uniformed Services. Military Treatment Facility (MTF) also refers to certain former U.S. Public Health Service (USPHS) facilities not designated as Uniformed Service Treatment Facilities (USTF).

Seizures: Use with caution in patients with a history of seizures or with conditions that lower the seizure threshold.
CODING FOR **ARISTADA INITIO** AND **ARISTADA**: AN OVERVIEW, *(CONT.)*

<table>
<thead>
<tr>
<th>POS code</th>
<th>Description</th>
</tr>
</thead>
</table>
| POS 50   | Federally Qualified Health Center  
A facility located in a medically underserved area that provides Medicare beneficiaries with preventive primary medical care under the general direction of a physician. |
| POS 51   | Inpatient Psychiatric Facility  
A facility that provides inpatient psychiatric services for the diagnosis and treatment of mental illness on a 24-hour basis, by or under the supervision of a physician. |
| POS 52   | Psychiatric Facility-Partial Hospitalization  
A facility for the diagnosis and treatment of mental illness that provides a planned therapeutic program for patients who do not require full time hospitalization, but who need broader programs than are possible from outpatient visits to a hospital-based or hospital-affiliated facility. |
| POS 53   | Community Mental Health Center  
A facility that provides the following services: outpatient services including specialized outpatient services for children, the elderly, individuals who are chronically ill, and residents of the CMHC’s mental health services area who have been discharged from inpatient treatment at a mental health facility; 24-hour-a-day emergency care services; day treatment, other partial hospitalization services, or psychosocial rehabilitation services; screening for patients being considered for admission to state mental health facilities to determine the appropriateness of such admission; and consultation and education services. |
| POS 56   | Psychiatric Residential Treatment Center  
A facility or distinct part of a facility for psychiatric care that provides a 24-hour therapeutically planned and professionally staffed group living and learning environment. |
| POS 71   | Public Health Clinic  
A facility maintained by either state or local health departments that provides ambulatory primary medical care under the general direction of a physician. |

Please refer to the POS guidance document published by CMS for additional information and descriptions associated with specific POS codes. This document can be accessed at: [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Website-POS-database.pdf](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Website-POS-database.pdf).

**IMPORTANT SAFETY INFORMATION, (cont.)**

**Potential for Cognitive and Motor Impairment:** ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil) 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.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for **ARISTADA INITIO** and **ARISTADA**.
COVERAGE AND REIMBURSEMENT FOR TREATMENT WITH ARISTADA INITIO AND ARISTADA BY SITE OF CARE

Provider office or Community Mental Health Center (CMHC)*
Coverage for ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil) administered in a CMHC or provider’s office varies by payer type.

State Medicaid programs use a variety of different reimbursement methods, including fee schedules, discounted charges, or other predetermined rates. Reimbursement for drugs is separate from professional services and may be based on Wholesale Acquisition Cost (WAC), invoice cost, a percentage of Average Sales Price (ASP), Average Wholesale Price (AWP), or other variable 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 separate from professional services and 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 different 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, invoice cost, a percentage of 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.

This is not a guarantee of payment, coverage, or reimbursement. Alkermes does not provide any advice, recommendation, guarantee, or warranty relating to coverage, reimbursement, or coding for any product or service. Healthcare providers are responsible for determining coverage and reimbursement information and ensuring the accuracy and completeness of claim submissions for their patients. Coding, coverage, and reimbursement vary significantly by payer, patient, and setting of care and are subject to change. Additional information may exist. Actual coverage and reimbursement decisions are made by individual payers. Contact insurer to confirm coverage of ARISTADA and/or ARISTADA INITIO.

IMPORTANT SAFETY INFORMATION, (cont.)

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.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Coding for treatment with ARISTADA INITIO and/or ARISTADA: claim forms CMS-1500/837P (physician offices and CMHCs)

The 837P (Professional) is the standard format used by healthcare professionals and suppliers to transmit claims electronically. The form CMS-1500 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.28

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 providers in a healthcare professional’s office who treat Medicare beneficiaries may use Form CMS-1500 (02/12) for most payers who accept paper claims if a paper claim is necessary.28

### ARISTADA INITIO® (aripiprazole lauroxil) Dosage Strengths and NDCs18

<table>
<thead>
<tr>
<th>Dosage Strength</th>
<th>11-Digit NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>675 mg</td>
<td>65757-0500-03</td>
</tr>
</tbody>
</table>

### ARISTADA® (aripiprazole lauroxil) Dosage Strengths and NDCs18

<table>
<thead>
<tr>
<th>Dosage Strength</th>
<th>11-Digit NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>441 mg</td>
<td>65757-0401-03</td>
</tr>
<tr>
<td>662 mg</td>
<td>65757-0402-03</td>
</tr>
<tr>
<td>882 mg</td>
<td>65757-0403-03</td>
</tr>
<tr>
<td>1064 mg</td>
<td>65757-0404-03</td>
</tr>
</tbody>
</table>

**IMPORTANT SAFETY INFORMATION, (cont.)**

**Dysphagia:** Esophageal dysmotility and aspiration have been associated with antipsychotic drug use; use caution in patients at risk for aspiration pneumonia.
**COVERAGE AND REIMBURSEMENT FOR TREATMENT WITH ARISTADA INITIO AND ARISTADA BY SITE OF CARE, (CONT.)**

Summary information for outpatient, physician office, or CMHC settings

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 and processes.

ARISTADA INITIO® (aripiprazole lauroxil) SUMMARY INFORMATION

<table>
<thead>
<tr>
<th>Code Set</th>
<th>Code</th>
<th>Description</th>
<th>Settings of Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS™</td>
<td>J3490</td>
<td>Unclassified drugs</td>
<td>Most payers and care settings</td>
</tr>
<tr>
<td>HCPCS™</td>
<td>C9399</td>
<td>Unclassified drugs or biologicals</td>
<td>Outpatient claims billed to Medicare under the Hospital Outpatient Prospective Payment System (OPPS)⁴</td>
</tr>
</tbody>
</table>

Procedural Codes for ARISTADA INITIO

<table>
<thead>
<tr>
<th>Code Set</th>
<th>Code</th>
<th>Description</th>
<th>Settings of Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT*</td>
<td>96372</td>
<td>Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular†</td>
<td></td>
</tr>
</tbody>
</table>

ARISTADA® (aripiprazole lauroxil) SUMMARY INFORMATION

<table>
<thead>
<tr>
<th>Code Set</th>
<th>Code</th>
<th>Description</th>
<th>Settings of Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS™</td>
<td>J1942</td>
<td>Injection, aripiprazole lauroxil, 1 mg</td>
<td>Most payers and care settings</td>
</tr>
</tbody>
</table>

Procedural Codes for ARISTADA

<table>
<thead>
<tr>
<th>Code Set</th>
<th>Code</th>
<th>Description</th>
<th>Settings of Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT*</td>
<td>96372</td>
<td>Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular†</td>
<td></td>
</tr>
</tbody>
</table>

**PLEASE 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.
- Most payers require additional information to be entered into Field 19 of the CMS-1500 claim form when an unclassified drug code is billed. The drug brand name, generic name, quantity administered, and route of administration are required (e.g., ARISTADA INITIO [aripiprazole lauroxil] 675 mg IM).
- To correctly reimburse Not Otherwise Classified (NOC) drugs and biologicals, providers must indicate the following in the 2400/SV101-7 data element, or Field 19 of the CMS-1500 claim form: the name of the drug, the total dosage (plus strength of dosage, if appropriate), and the method of administration.

ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification
DSM=American Psychiatric Association, Diagnostic and Statistical Manual
CPT*®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association.
* This code is not intended to be reported by the physician in the facility setting.
† ARISTADA INITIO and ARISTADA are administered as IM injections only.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
<table>
<thead>
<tr>
<th>Field/Category Name</th>
<th>ARISTADA INITIO* (aripiprazole lauroxil) Example*</th>
<th>ARISTADA* (aripiprazole lauroxil) Example*</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 (e.g., NDCs)</td>
<td>675 mg: NDC 65757-0500-03</td>
<td>441 mg: NDC 65757-0401-03</td>
<td>837P Loop ID, Segment/Data Element</td>
<td>CMS-1500 (02/12) Field Number</td>
</tr>
<tr>
<td>Procedures, Services, or Supplies (e.g., CPT* code)</td>
<td>96372 therapeutic, prophylactic, or diagnostic injection</td>
<td>96372 therapeutic, prophylactic, or diagnostic injection</td>
<td>Loop 2400/SV101</td>
<td>Field 24D</td>
</tr>
<tr>
<td>Procedures, Services, or Supplies (e.g., CPT* code)</td>
<td>J3490</td>
<td>J1942</td>
<td>Loop 2400/SV104</td>
<td>Field 24G</td>
</tr>
<tr>
<td>Units</td>
<td>1 unit for 675 mg (When utilizing the miscellaneous J-code: J3490)</td>
<td>441 units for 441 mg 662 units for 662 mg 882 units for 882 mg 1064 units for 1064 mg</td>
<td>Loop 2400/SV101</td>
<td>Field 19</td>
</tr>
<tr>
<td>Diagnosis or Nature of Illness or Injury</td>
<td>Input appropriate diagnosis code</td>
<td>Input appropriate diagnosis code</td>
<td>Loop 2300/HI10-2 to HI12-2</td>
<td>Field 21</td>
</tr>
</tbody>
</table>


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

† This code is not intended to be reported by the physician in the facility setting.

‡ ARISTADA INITIO and ARISTADA are administered as IM injections only.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
**SAMPLE CMS-1500 CLAIM FORM (PHYSICIAN OFFICE BILLING)\n
ARISTADA INITIO AND ARISTADA SAME-DAY ADMINISTRATION**

**RECORDING DRUG ADMINISTRATION**

- ARISTADA INITIO® (aripiprazole lauroxil) and ARISTADA® (aripiprazole lauroxil) may be administered on the same day.

- The following example provides guidance for billing forms when drug administration happens on the same date—ARISTADA INITIO 675 mg and ARISTADA 662 mg are administered on July 1, 2018.

<table>
<thead>
<tr>
<th>Date</th>
<th>Procedure Code</th>
<th>Description</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/01/18</td>
<td>J3490</td>
<td>ARISTADA INITIO 675</td>
<td>1</td>
</tr>
<tr>
<td>07/01/18</td>
<td>C3499</td>
<td>ARISTADA INITIO 675</td>
<td>1</td>
</tr>
<tr>
<td>07/01/18</td>
<td>96372</td>
<td>ARISTADA 662</td>
<td>1</td>
</tr>
<tr>
<td>07/01/18</td>
<td>96372</td>
<td>ARISTADA 662</td>
<td>1</td>
</tr>
</tbody>
</table>

**IMPORTANT SAFETY INFORMATION, (cont.)**

**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.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
COMPLETING THE CMS-1500 CLAIM FORM
ARISTADA INITIO AND ARISTADA SAME-DAY ADMINISTRATION

1. DIAGNOSIS CODE (Field 21)
Enter ICD-10-CM codes appropriate for the patient.

2. PRIOR AUTHORIZATION NUMBER (Field 23)
Document Prior Authorization number issued by the payer, if one is required.

3. PRODUCT CODE (Field 24D)
Document product use with HCPCS code, J3490 for ARISTADA INITIO® (aripiprazole lauroxil) and J1942 for ARISTADA® (aripiprazole lauroxil).

4. DIAGNOSIS POINTER (Field 24E)
Specify diagnosis, from Field 21, for each HCPCS/CPT® code listed.

5. SERVICE UNITS (Field 24G)
a. Report number of units of ARISTADA INITIO. Enter 1 unit when utilizing J3490 or C3499. (One unit of either code is equal to 675 mg).

b. Report number of units of ARISTADA (one unit of J1942 is equal to 1 mg):
   • 441 units for 441 mg
   • 882 units for 882 mg
   • 662 units for 662 mg
   • 1064 units for 1064 mg

Note: Some payers may require a drug to be billed over two lines due to limitations in the amount of digits allowed in Field 24G. For example, when administering 1064 mg of ARISTADA, one line of J1942 would be represented as 999 service units and the second line of J1942 would be represented with 65 service units.

6. PROCEDURE CODE (Field 24D)
Document administration of ARISTADA INITIO and ARISTADA with CPT® code 96372 (therapeutic, prophylactic, or diagnostic injection [specify substance or drug], subcutaneous or intramuscular*). For some payers, the use of modifier 59 may be appropriate when performing 2 injections on the same visit.

7. ADDITIONAL CLAIM INFORMATION (Field 19)
Most payers require additional information to be inputted into Box 19 of the CMS-1500 claim form when an unclassified drug code is billed. The drug brand name, generic name, quantity administered, and route of administration are required.
Example: ARISTADA INITIO ARIPIPRAZOLE LAUROXIL 675 MG IM 65757-0500-03

CPT®=Current Procedural Terminology, CPT® is a registered trademark of the American Medical Association.
* ARISTADA INITIO and ARISTADA are administered as IM injections only.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
SAMPLE CMS-1500 CLAIM FORM
(physician office billing)
ARISTADA-ONLY* ADMINISTRATION

Please verify with the payer any character/digit limitations, e.g., 3-digit limitation in Field 24G (Days or Units) when billing for the 1064 mg dose of ARISTADA® (aripiprazole lauroxil).

Field 24G
Some payers may not allow 4 digits in Field 24G. Please confirm billing guidelines with the payer.

Note: See sample below for split-line billing if payer cannot accept 4 digits in Field 24G

For payers that do not allow 4-digit billing in Field 24G, please see the method below for billing the 1064 mg dose.

ARISTADA 1064 mg
ADMINISTERED ON JULY 1, 2018
(Shown here as July 1, 2018 for example purposes only)

See Appendix for CMS-1500 coding example for administration of ARISTADA INITIO® (aripiprazole lauroxil) only.

* In conjunction with 21 consecutive days of oral aripiprazole supplementation.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
COMPLETING THE CMS-1500 CLAIM FORM

ARISTADA-ONLY* ADMINISTRATION

1. DIAGNOSIS CODE (Field 21)
Enter ICD-10-CM codes appropriate for the patient.

2. PRIOR AUTHORIZATION NUMBER (Field 23)
Document Prior Authorization number issued by the payer, if one is required.

3. PRODUCT CODE (Field 24D)

4. DIAGNOSIS POINTER (Field 24E)
Specify diagnosis, from Field 21, for each HCPCS/CPT® code listed.

5. SERVICE UNITS (Field 24G)
Report number of units of ARISTADA* (aripiprazole lauroxil) (one unit of J1942 is equal to 1 mg):
- 441 units for 441 mg
- 662 units for 662 mg
- 882 units for 882 mg
- 1064 units for 1064 mg

Note: Some payers may require a drug to be billed over two lines due to limitations in the amount of digits allowed in Field 24G. For example, when administering 1064 mg of ARISTADA, one line of J1942 would be represented as 999 units and the second line of J1942 would be represented with 65 units.

6. PROCEDURE CODE (Field 24D)
Document administration of ARISTADA with CPT® code 96372 (therapeutic, prophylactic, or diagnostic injection [specify substance or drug], subcutaneous or intramuscular†).


* In conjunction with 21 consecutive days of oral aripiprazole supplementation.
† ARISTADA is administered as an IM injection only.

IMPORTANT SAFETY INFORMATION, (cont.)

Concomitant Medication, (cont.): 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.)

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Channels for obtaining ARISTADA INITIO and/or ARISTADA: provider office/CMHC

One channel for obtaining ARISTADA INITIO and/or ARISTADA for administration in a provider office or CMHC is buy-and-bill, where the practice purchases the medication from a specialty distributor and then bills the payer for administration and the cost of the product based on a prenegotiated fee schedule.

In some cases, payers may require that drugs be acquired from a designated distributor or SPP and be shipped to the site of care for administration to the patient. This process is also sometimes known as “white bagging.” Contact the patient’s insurance plan to determine coverage and requirements for acquisition of provider-administered drugs.

IMPORTANT SAFETY INFORMATION, (cont.)

Commonly Observed Adverse Reactions: In pharmacokinetic studies the safety profile of ARISTADA INITIO® (aripiprazole lauroxil) was generally consistent with that observed for ARISTADA® (aripiprazole lauroxil). 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.
HOSPITAL OUTPATIENT BILLING & CODING

Hospital outpatient or partial hospitalization CMHCs

Coverage for ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil) when administered in the hospital outpatient (POS 22), Psychiatric Facility-Partial Hospitalization (POS 52), or partial hospitalization in the CMHC setting (POS 53) may vary by payer type. Organizations should use the appropriate POS code based on their structure or services or otherwise consistent with their organizational guidance when filing claims.

State Medicaid programs use a variety of payment methodologies: Maximum Allowable Cost (MAC) cost-sharing limits, discounted charges, 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 Wholesale Acquisition Cost (WAC), Average Wholesale Price (AWP), invoice cost, or a percentage of Average Sales Price (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 OPPS and payment is based on APCs. 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 box on the following page). CMHCs that meet the Medicare criteria may be able to bill Medicare for partial hospitalization through hospital OPPS.30

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 prenegotiated rates.

IMPORTANT SAFETY INFORMATION, (cont.)

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%.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Hospital outpatient or partial hospitalization coding for treatment with ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil): claim form UB-04/CMS-1450/837I

The 837I (Institutional) is the standard format used by institutional providers to transmit claims electronically. The form UB-04, also known as the CMS-1450, is the standard claim form to bill Medicare Administrative Contractors (MACs) 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.31 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.

Medicare criteria for CMHC to provide partial hospitalization services (POS 53)

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 screening and evaluation for clients being considered for admission to state mental health facilities
- It provides at least 40% of its services to individuals who are not eligible for benefits under Medicare
- Services are furnished under the general supervision of a physician
- Services are subject to certification that the individual patient would require inpatient psychiatric care if partial hospitalization services were not provided
- Services are provided under an individualized treatment plan

IMPORTANT SAFETY INFORMATION, (cont.)

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 other’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 additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
<table>
<thead>
<tr>
<th>Field/ Category Name</th>
<th>ARISTADA INITIO® (aripiprazole lauroxil) Example</th>
<th>ARISTADA® (aripiprazole lauroxil) Example</th>
<th>837I Loop ID, Segment/Data Element</th>
<th>UB-04/CMS-1450</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)  
| Loop 2400, SV201    | Check with payer (instructions may vary)     | Field 42                             | Field 43                         |
| Description         | Medicare requirements for claims crossing over to Medicaid include the NDC qualifier N4 followed by the 11-digit NDC (e.g., N465757-0500-03)  
|                      | Medicare requirements for claims crossing over to Medicaid include the NDC qualifier N4 followed by the 11-digit NDC (e.g., N465757-XXXX-03)  
|                      | J3490 for ARISTADA INITIO  
C9399 to be utilized for Medicare Outpatient Claims  
|                      | J1942 for ARISTADA | Loop 2400, SV202-2 | Field 44 |
| CPT® Code*          | 96372 (therapeutic, prophylactic, or diagnostic injection)†  
|                      | 96372 (therapeutic, prophylactic, or diagnostic injection)†  
|                      | Loop 2400, SV205 | Loop 2400, SV205 | Field 46 |
| HCPCS Code          | J3490 for ARISTADA INITIO  
C9399 to be utilized for Medicare Outpatient Claims  
|                      | J1942 for ARISTADA | Loop 2400, SV202-2 | Field 44 |
| Service Units       | 1 unit for 675 mg (when utilizing the miscellaneous J-code: J3490)  
|                      | 441 units for 441 mg  
662 units for 662 mg  
882 units for 882 mg  
1064 units for 1064 mg  
|                      | Loop 2300, HI01-2 (HI01-1=BK)  
|                      | Fields 67A-Q | Loop 2400, SV205 | Field 46 |
| Diagnosis           | Input appropriate diagnosis code  
|                      | Input appropriate diagnosis code  
|                      | Loop 2300, HI01-2 (HI01-1=BK)  
|                      | Fields 67A-Q | Loop 2400, SV205 | Field 46 |

† This code is not intended to be reported by the physician in the facility setting.  
* ARISTADA INITIO and ARISTADA are administered as IM injections only.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
SAMPLE CMS-1450 CLAIM FORM (HOSPITAL BILLING)

ARISTADA INITIO AND ARISTADA SAME-DAY ADMINISTRATION

RECORDING DRUG ADMINISTRATION

• ARISTADA INITIO® (aripiprazole lauroxil) and ARISTADA® (aripiprazole lauroxil) may be administered on the same day

• The following example provides guidance for billing forms when drug administration happens on the same date—ARISTADA INITIO 675 mg and ARISTADA 662 mg are administered on July 1, 2018

Ensure the correct dosage is listed for ARISTADA
• 441 units for 441 mg
• 662 units for 662 mg
• 882 units for 882 mg
• 1064 units for 1064 mg

Note: Enter 1 unit for ARISTADA INITIO when utilizing J3490 or C3499

ARISTADA INITIO 675 mg AND ARISTADA 662 mg BOTH ADMINISTERED ON SAME DATE (Shown here as July 1, 2018 for example purposes only)

ARISTADA INITIO ARIPIPRAZOLE LAUROXIL 675MG IM 65757-0500-03

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
COMPLETING THE CMS-1450 CLAIM FORM
ARISTADA INITIO AND ARISTADA SAME-DAY ADMINISTRATION

1. REVENUE CODE (Field 42)
   For unclassified drug codes revenue code 0636 (drugs that require detailed coding) may be appropriate due to additional information being reported in Box 80.

2. DESCRIPTION (Field 43)
   Include the NDC information for ARISTADA INITIO® (aripiprazole lauroxil) that includes the NDC qualifier N4 followed by the 11-digit NDC, unit of measure, and quantity delivered to the patient.

3. HCPCS CODE (Field 44)
   In Field 44, enter the applicable HCPCS or CPT® code (including any modifiers needed) to describe the drug and other separately billable services provided.
   - HCPCS: J3490 should be used for ARISTADA INITIO billed to commercial payers and Medicaid
   - J1942 should be used for ARISTADA® (aripiprazole lauroxil)
   - C9399 should be used for ARISTADA INITIO billed to Medicare in the outpatient setting
   - HCPCS (CPT*) procedure example: 96372 (therapeutic, prophylactic, or diagnostic injection [specify substance or drug], subcutaneous or intramuscular*)

4. SERVICE UNITS (Field 46)
   a. Report number of units of ARISTADA INITIO. Enter 1 unit when utilizing J3490 or C3499. (One unit of either code is equal to 675 mg).
   b. Report number of units of ARISTADA (one unit of J1942 is equal to 1 mg):
      - 441 units for 441 mg
      - 882 units for 882 mg
      - 662 units for 662 mg
      - 1064 units for 1064 mg

5. DIAGNOSIS CODE (Field 67)
   Enter the appropriate ICD-10 codes for the patient. This field should contain the ICD-10 diagnosis code that describes the primary reason that the patient is receiving the outpatient services described on the claim. Additional diagnosis codes should be included within Fields 67A-Q.

6. REMARKS (Field 80)
   This field should be filled out when an unclassified drug code is billed. The box includes the drug brand name, generic name, quantity administered and route of administration; e.g. ARISTADA INITIO ARIPIPRAZOLE LAUROXIL 675 MG IM 65757-0500-03.

* ARISTADA INITIO and ARISTADA are administered as IM injections only.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
SAMPLE CMS-1450 CLAIM FORM (HOSPITAL BILLING)

ARISTADA INITIO AND ARISTADA DIFFERENT DAY ADMINISTRATION

RECORDING DRUG ADMINISTRATION

- The first ARISTADA® (aripiprazole lauroxil) injection may be administered up to 10 days after ARISTADA INITIO® (aripiprazole lauroxil)
- The following example provides guidance for billing forms when drug administration happens on different dates—ARISTADA INITIO 675 mg is administered on July 1, 2018, while ARISTADA 662 mg is administered on July 9, 2018

Field 80
Should be utilized when billing an unclassified code.

Ensure the correct dosage is listed for ARISTADA
- 441 units for 441 mg
- 662 units for 662 mg
- 882 units for 882 mg
- 1064 units for 1064 mg

Enter 1 unit for ARISTADA INITIO when utilizing J3490 or C3499

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
COMPLETING THE CMS-1450 CLAIM FORM
ARISTADA INITIO AND ARISTADA DIFFERENT DAY ADMINISTRATION

1. **REVENUE CODE (Field 42)**
   For unclassified drug codes revenue code 0636 (drugs that require detailed coding) may be appropriate due to additional information being reported in Box 80.

2. **DESCRIPTION (Field 43)**
   Include the NDC information for ARISTADA INITIO® (aripiprazole lauroxil) that includes the NDC qualifier N4 followed by the 11-digit NDC, unit of measure and quantity delivered to the patient.

3. **HCPCS CODE (Field 44)**
   In Field 44, enter the applicable HCPCS or CPT® code (including any modifiers needed) to describe the drug and other separately billable services provided.
   - **HCPCS:** J3490 should be used for ARISTADA INITIO billed to commercial payers and Medicaid
   - C9399 should be used for ARISTADA INITIO billed to Medicare in the outpatient setting
   **HCPCS (CPT®) procedure example:** 96372 (therapeutic, prophylactic, or diagnostic injection [specify substance or drug], subcutaneous or intramuscular*)

4. **SERVICE UNITS (Field 46)**
   a. Report number of units of ARISTADA INITIO. Enter 1 unit when utilizing J3490 or C3499. (One unit of either code is equal to 675 mg).
   b. Report number of units of ARISTADA® (aripiprazole lauroxil) (one unit of J1942 is equal to 1 mg):
      - 441 units for 441 mg
      - 662 units for 662 mg
      - 882 units for 882 mg
      - 1064 units for 1064 mg

5. **DIAGNOSIS CODE (Field 67)**
   Enter the appropriate ICD-10 codes for the patient. This field should contain the ICD-10 diagnosis code that describes the primary reason that the patient is receiving the outpatient services described on the claim. Additional diagnosis codes should be included within Fields 67A-Q.

6. **REMARKS (Field 80)**
   This field should be filled out when an unclassified drug code is billed. The box includes the drug brand name, generic name, quantity administered and route of administration; e.g. ARISTADA INITIO ARIPIPRAZOLE LAUROXIL 675 MG IM 65757-0500-03.

* ARISTADA INITIO and ARISTADA are administered as IM injections only.
Please verify with the payer any character/digit limitations, e.g., 3-digit limitation in Field 46 (Service Units) when billing for the 1064 mg dose of ARISTADA® (aripiprazole lauroxil).

<table>
<thead>
<tr>
<th>Field 46</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some payers may not allow 4 digits in Field 46. Please confirm billing guidelines with the payer. Note: See sample below for split-line billing if payer cannot accept 4 digits in Field 46.</td>
</tr>
</tbody>
</table>

For payers that do not allow 4-digit billing in Field 46, please see the method below for billing the 1064 mg dose.

<table>
<thead>
<tr>
<th>Field 46</th>
</tr>
</thead>
<tbody>
<tr>
<td>When billing 1064 units and payer requires 3 digits, split the units over 2 lines: 999+65 = 1064 units</td>
</tr>
</tbody>
</table>

ARISTADA 1064 mg
ADMINISTERED ON JULY 1, 2018
(Shown here as July 1, 2018 for example purposes only)

* In conjunction with 21 consecutive days of oral aripiprazole supplementation.
COMPLETING THE CMS-1450 CLAIM FORM

ARISTADA-ONLY* ADMINISTRATION

1 REVENUE CODE (Field 42)
Enter the appropriate revenue code(s).

Revenue code examples:
• For Medicare, revenue code 0636 (drugs that require detailed coding) may be appropriate
• For Non-Medicare payers, revenue code 0250 (general pharmacy) may be appropriate
• Injection services may be reported with revenue code 0510 (clinic, general service)

2 DESCRIPTION (Field 43)
This field is not required. However, for Medicare claims where Medicaid is the secondary payer, Field 43 should be used to report drug rebate information for Medicaid crossover purposes. The format required by Medicare includes the NDC qualifier N4 followed by the 11-digit NDC in positions 01-13 (e.g., N465757-XXXX-03). Report the NDC quantity qualifier followed by the quantity beginning in position 14. The Description Field on Form CMS-1450 is 24 characters long.

3 HCPCS CODE (Field 44)
In Field 44, enter the applicable HCPCS or CPT® code (including any modifiers needed) to describe the drug and other separately billable services provided.

HCPCS: J1942 should be used for ARISTADA® (aripiprazole lauroxil)
HCPCS (CPT®) procedure example: 96372 (therapeutic, prophylactic, or diagnostic injection [specify substance or drug], subcutaneous or intramuscular†)

4 SERVICE UNITS (Field 46)
Report number of units of ARISTADA® (aripiprazole lauroxil) (one unit of J1942 is equal to 1 mg):
• 441 units for 441 mg
• 882 units for 882 mg
• 662 units for 662 mg
• 1064 units for 1064 mg

5 DIAGNOSIS CODE (Field 67)
Enter the appropriate ICD-10 codes for the patient. This field should contain the ICD-10 diagnosis code that describes the primary reason that the patient is receiving the outpatient services described on the claim. Additional diagnosis codes should be included within Fields 67A-Q.

* In conjunction with 21 consecutive days of oral aripiprazole supplementation.
† ARISTADA is administered as an IM injection only.
Hospital outpatient and Ambulatory Payment Classifications (APCs)

Under the Medicare hospital OPPS, most services are reimbursed based on groups of procedures known as Ambulatory Payment Classifications (APCs). The information in the table below shows the mapping of HCPCS codes entered onto the claim form to APCs that may be appropriate for treatment with ARISTADA® (aripiprazole lauroxil).

Please note, the code for ARISTADA INITIO® (aripiprazole lauroxil) will not route to an APC.

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
<th>Maps to APC</th>
<th>HCPCS Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®23*</td>
<td>96372</td>
<td>0436</td>
<td>Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular*</td>
</tr>
<tr>
<td>HCPCS19</td>
<td>J1942</td>
<td>9470</td>
<td>Injection, aripiprazole lauroxil, 1 mg</td>
</tr>
</tbody>
</table>

* ARISTADA is administered as an IM injection only.

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**
- Documentation, as needed, if a step edit exists
- Attaching prescribing information

**Claim form completion and submission**
- Use the claim form and preferred format (e.g., electronic or paper) designated by the payer
- Identify correct date of service
- Provide correct and accurate coding
- Correctly specify number of 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

Channels for obtaining ARISTADA INITIO and/or ARISTADA: hospital outpatient settings

In most cases, drugs administered in the hospital outpatient setting will be obtained through normal hospital procurement channels. Contact ARISTADA Care Support (1-866-ARISTADA [1-866-274-7823]) or your Territory Business Manager for questions on how to obtain ARISTADA INITIO and/or ARISTADA.
HOSPITAL INPATIENT BILLING & CODING

Coverage for ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil) 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)
- Global case rates
- Per diem rates

Medicaid

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

Medicare reimburses for most hospital inpatient stays (except for psychiatric hospitals and most inpatient psychiatric units) according to a prospective payment system based on DRGs. These are determined by the ICD-10 diagnostic 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 global MS-DRG payment per patient inpatient stay and under certain circumstances are also eligible for additional outlier payments. Drugs such as ARISTADA INITIO and/or ARISTADA are typically not reimbursed separately.

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

Commercial payers may cover inpatient treatment with ARISTADA INITIO and/or ARISTADA in several different ways. Many payers use a global payment rate that includes most or all services and medications that are usually based on modified MS-DRGs and does not include a separate payment for drugs. Other commercial and managed care plans reimburse based on case rates, Usual, Customary and Reasonable (UCR) 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.
## Payment Methodologies for Hospital Inpatient

<table>
<thead>
<tr>
<th>Medicaid</th>
<th>Medicare</th>
<th>Commercial</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inpatient Hospital Payment</strong></td>
<td><strong>Inpatient Drug Payment</strong></td>
<td><strong>Inpatient Hospital Payment</strong></td>
</tr>
<tr>
<td>• Payment methodology varies by state</td>
<td>• Drug payment is usually included in DRG or per diem bundled payments</td>
<td>• Payment methodology varies by plan although most use a global rate or per diem rate</td>
</tr>
<tr>
<td>• Variations of DRG bundled-payment systems or per diems, such as MS-DRGs or APR-DRGs</td>
<td>• Drug payment is included in MS-DRG or per diem bundled payment</td>
<td></td>
</tr>
<tr>
<td>• Bundled payment based on MS-DRGs except for inpatient psychiatric facilities and units, which are paid on a per diem basis</td>
<td>• Drug payment is included in DRG or per diem bundled payments</td>
<td></td>
</tr>
<tr>
<td>• Payments will vary based on complications and comorbidities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• For more information, review the Medicare Prospective Payment System (PPS) fee schedule for hospital inpatient services at: <a href="http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PCPricer/inpatient.html">http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PCPricer/inpatient.html</a></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
PRIOR AUTHORIZATION (PA), EXCEPTIONS, AND APPEALS FOR TREATMENT WITH ARISTADA INITIO AND/OR ARISTADA

Payers often require PAs for mental health services. For antipsychotic medications, PAs generally are based on clinical criteria (e.g., the patient’s diagnosis and on-label use of the medication). Some payers allow the healthcare professional to request a PA by telephone, or to submit PA requests electronically. However, for treatments that are considered expensive, payers may require a written request for treatment and require specific documentation from the healthcare professional. Payers also may have specific forms that must be completed for a PA. The letter within this section is an example of a Letter of Medical Necessity (LOMN) for use when requesting PA or a formulary exception for ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil).

In some cases and geographies, ARISTADA INITIO and/or ARISTADA may be in a drug category that is protected to ensure patient access. Please refer to the Benefit Verification Tips section of this guide for more information about the importance of a thorough benefit investigation prior to treatment.

If, during the benefit investigation, it is determined that ARISTADA INITIO and/or ARISTADA are listed as “not covered” on the payer’s formulary and a patient needs treatment with ARISTADA INITIO and/or ARISTADA, the healthcare professional can submit an appeal for coverage, or a formulary exception.

General guidance for seeking prior authorization or a formulary exception is as follows:

- Ask the payer about the preferred format for PA requests and whether there is a product-specific or category-specific PA request form for long-acting injectable antipsychotics such as ARISTADA INITIO and/or ARISTADA
- Determine the documentation the payer may accept to support the request, such as a Letter of Medical Necessity, patient history, and chart notes
- If unfamiliar with the coverage of ARISTADA INITIO and/or ARISTADA, contact the payer to discuss coverage for the patient

ARISTADA Care Support is available to help identify a payer’s coverage and to assist in obtaining access for a patient. Contact the ARISTADA care support at 1-866-ARISTADA (1-866-274-7823).
PRIOR AUTHORIZATION (PA), EXCEPTIONS, AND APPEALS FOR TREATMENT WITH ARISTADA INITIO AND/OR ARISTADA, (CONT.)

Checklist for requesting prior authorization

During the initial benefit verification process, determine whether the payer requires a PA for ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil), and what the criteria are for PA approval.

- If PA is required, ask whether plan has a product-specific PA form and where it can be obtained
- Ask whether a PA can be submitted electronically
- Obtain the telephone number or fax number for the PA department
- Ask the contact to explain the PA process, and whether it requires any special forms, or a Letter of Medical Necessity (LOMN)
- Inquire how long the process will take, once the necessary forms and documentation are submitted
- If the time frame for obtaining ARISTADA INITIO and/or ARISTADA is urgent, ask whether there are procedures for expediting the request on behalf of the patient

Contact ARISTADA Care Support (1-866-ARISTADA [1-866-274-7823]) for support and assistance with prior authorization, and patient access for ARISTADA.

Formulary exceptions for ARISTADA INITIO and/or ARISTADA

ARISTADA is a medication that was approved by the FDA in October 2015. ARISTADA INITIO is a medication that was approved by the FDA in June 2018. In some cases and geographies, ARISTADA INITIO and/or ARISTADA may be in a drug category that is protected to ensure patient access.

If a benefit investigation determines that ARISTADA INITIO and/or ARISTADA is listed as “not covered” on the payers’ formulary, healthcare professionals can submit an appeal for coverage, or a formulary exception request. Most payers provide an option to request approval using a process that is similar to submission of a request for a PA.

For patients covered by Medicare, including patients with coverage under both Medicare and Medicaid (dual eligible), Part D plans are required to have a formulary exception process. Appropriate forms can be obtained from the Medicare Part D appeals website (http://www.medicarepartdappeals.com).
Sample LOMN to support prior authorization/formulary exception request for ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil)

Prior Authorization (PA), Exceptions, and Appeals for Treatment with ARISTADA INITIO and/or ARISTADA, (CONT.)

<table>
<thead>
<tr>
<th>Payer Contact Name:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Title:</td>
<td></td>
</tr>
<tr>
<td>Name of Health Insurance Company:</td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td>City, State, ZIP Code:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Information:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name:</td>
<td>Insured Name:</td>
</tr>
<tr>
<td>Policy Number:</td>
<td>Group Number:</td>
</tr>
</tbody>
</table>

| Schizophrenia Diagnosis Code(s): |  |

Dear [Name of contact],

I am writing on behalf of my patient, [Patient name], to request prior authorization for ARISTADA® (aripiprazole lauroxil) long-acting injectable atypical antipsychotic. The patient will be treated with ARISTADA for [Patient's diagnosis]. ARISTADA is indicated for the treatment of schizophrenia.

This letter outlines [Patient name] medical history, prognosis, and treatment rationale.

Summary of Patient History:

- Patient's diagnosis, condition, and history:

- Previous treatments the patient has taken for the symptoms associated with [Patient's disease state]:

- Patient's response to previous treatments:

- Description of the patient's recent symptoms:

- Need for ARISTADA:

Based on these facts, ARISTADA is indicated and medically necessary for this patient.

If you have further questions, please feel free to call me at [XXX-XXX-XXX] to discuss.

Thank you in advance for your immediate attention to this request.

Sincerely,

[Name]

Name of Practice

Address of Practice

Please see additional Important Safety Information on the following pages and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Managing PA denials

If the healthcare professional receives a PA denial because a payer does not cover ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA* (aripiprazole lauroxil), resubmit the request with additional documentation supporting medical necessity. The healthcare professional may also call ARISTADA Care Support at 1-866-ARISTADA (1-866-274-7823) for assistance.

If the healthcare professional has not done so previously, it is strongly recommended to include a detailed LOMN in the appeal packet. Please see the sample LOMN for examples of the types of information that should be included.

In addition, the healthcare professional should 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 journal articles supporting the use of ARISTADA INITIO and/or ARISTADA.

If the second submission is denied, it may be necessary to contact the payer’s medical director. PA denials may be reversed following medical review of an accurate and complete appeal request.

Appealing a claim denial

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 following checklist provides some tips for appealing denied claims:

### CHECKLIST 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:
  - What information must be included with the appeal (e.g., a copy of the original claim, EOB, LOMN, 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 identification numbers, coding and additional information requested
- 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)

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Sample appeals letter for ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil)

### Appeal Letter

<table>
<thead>
<tr>
<th>Payer Contact Name:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Title:</td>
<td></td>
</tr>
<tr>
<td>Name of Health Insurance Company:</td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td>City, State, ZIP Code:</td>
<td></td>
</tr>
</tbody>
</table>

**Patient Information:**
- **Patient Name:**
- **Insured Name:**
- **Policy Number:**
- **Group Number:**

<table>
<thead>
<tr>
<th>Schizophrenia Diagnosis Code(s):</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Claim Number:</td>
<td></td>
</tr>
</tbody>
</table>

Dear [Name]:

This letter serves as a request for reconsideration of payment for a claim representing charges for ARISTADA® (aripiprazole lauroxil) administered to [Patient's name] on [Date of service]. [Patient's name] has been under my treatment for [his/her] diagnosis of [Diagnosis]. You have indicated ARISTADA® is not covered by [Insurer's name] because [Reason for denial]. ARISTADA® is indicated for the treatment of schizophrenia. Because of [insert relevant patient information/history, diagnosis, specifics of medical necessity versus other therapy alternative], I have administered as a medically necessary part of this patient's treatment and request your reconsideration of the denied claim for [his/her] [Patient's name]. Please contact me at [Phone number] if you require additional information.

Thank you in advance for your immediate attention to this request.

Sincerely,

<table>
<thead>
<tr>
<th>Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Practice</td>
<td></td>
</tr>
<tr>
<td>Address of Practice</td>
<td></td>
</tr>
</tbody>
</table>

**Attachments**
- Original Claim Form
- Letter of Medical Necessity
- Explanation of Benefits
- Additional Supporting Documents

Please see additional Important Safety Information on the following pages and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
ARISTADA INITIO

INDICATION

ARISTADA INITIO® (aripiprazole lauroxil), in combination with oral aripiprazole, is indicated for the initiation of ARISTADA® (aripiprazole lauroxil) when used for the treatment of schizophrenia in adults.34

ARISTADA is indicated for the treatment of schizophrenia in adults.34

INITIATION DOSING

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.34

To initiate treatment with ARISTADA INITIO:

**STEP 1**

After establishing tolerability with oral aripiprazole, give patients a one-time ARISTADA INITIO injection and a single 30 mg dose of oral aripiprazole34

**DAY 1**

1 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 desired35

441 mg  662 mg  882 mg  1064 mg

**FIRST ARISTADA DOSE**

This is not all the information needed for dosing and administering ARISTADA INITIO and ARISTADA. Please consult the full Prescribing Information for both products.

### ARISTADA INITIO34

<table>
<thead>
<tr>
<th>ARISTADA INITIO Dosage Strength</th>
<th>Dosing Interval</th>
<th>Intramuscular Injection Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>675 mg</td>
<td>Single Dose Only - Not for Repeated Dosing</td>
<td>GLUTEAL or DELTOID</td>
</tr>
</tbody>
</table>

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
ARISTADA INITIO, (CONT.)

How supplied
ARISTADA INITIO® (aripiprazole lauroxil) extended-release injectable suspension is supplied in one dosage strength of 675 mg in 2.4 mL.34

• A 675 mg strength kit (NDC 65757-0500-03; grey label) contains a 5-mL pre-filled syringe containing ARISTADA INITIO sterile aqueous suspension and three safety needles; a 1-inch (25 mm) 21 gauge, a 1½-inch (38 mm) 20 gauge, and a 2-inch (50 mm) 20 gauge needle34

Storage
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.34

• Store each product properly per instructions on carton(s)34

• 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 sediment near needle hub36
ARISTADA

INDICATION
ARISTADA® (aripiprazole lauroxil) is indicated for the treatment of schizophrenia in adults.35

RECOMMENDED DOSING
Depending on individual patient’s needs, treatment with ARISTADA can be started at any dose: 441 mg, 662 mg or 882 mg administered monthly, 882 mg administered every 6 weeks, or 1064 mg administered every 2 months.35 ARISTADA treatment can be initiated with the ARISTADA INITIO® (aripiprazole lauroxil) regimen, or by supplementing with 21 consecutive days of oral aripiprazole with the first ARISTADA injection.34

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.34

For patients who have never taken aripiprazole, establish tolerability with oral aripiprazole prior to initiating treatment with ARISTADA or ARISTADA INITIO.34

ARISTADA INITIO and ARISTADA are not interchangeable because of differing pharmacokinetic profiles.34

ARISTADA INITIO and ARISTADA are only to be administered as an intramuscular injection by a healthcare professional.34

ARISTADA INITIO can be administered in the deltoid or gluteal muscle. ARISTADA can be administered in the gluteal muscle (all doses) or deltoid muscle (441 mg only). Avoid injecting both ARISTADA and ARISTADA INITIO concomitantly into the same deltoid or gluteal muscle.34

DOSE ADJUSTMENT CONSIDERATIONS FOR ARISTADA INITIO
No dose adjustments of ARISTADA INITIO can be made.34

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.34

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
**ARISTADA, (CONT.)**

**DOSE ADJUSTMENT CONSIDERATIONS FOR ARISTADA**

Refer to the oral aripiprazole Prescribing Information for recommendations regarding dosage adjustments due to drug interactions for the first 21 days when the patient is taking oral aripiprazole concomitantly with the first dose of ARISTADA® (aripiprazole lauroxil).35

Once stabilized on ARISTADA, refer to the dosing recommendations below for patients taking strong CYP2D6 inhibitors, strong CYP3A4 inhibitors, or strong CYP3A4 inducers:

- No dosage changes are recommended for ARISTADA if CYP450 modulators are added for less than 2 weeks35
- Make the following dose changes to ARISTADA if CYP450 modulators are added for greater than 2 weeks35
- Depending on the ARISTADA dose, adjustments may be recommended. Refer to the table below:

**ARISTADA DOSE ADJUSTMENTS WITH CONCOMITANT CYP450 MODULATOR USE**

<table>
<thead>
<tr>
<th>Concomitant Medicine</th>
<th>Dose Change for ARISTADA35</th>
</tr>
</thead>
</table>
| Strong CYP3A4 Inhibitor              | Reduce the dose of ARISTADA to the next lower strength. No dosage adjustment is necessary in patients taking 441 mg ARISTADA, if tolerated.  
  *For patients known to be poor metabolizers of CYP2D6:* Reduce dose to 441 mg from 662 mg, 882 mg or 1064 mg. No dosage adjustment is necessary in patients taking 441 mg ARISTADA, if tolerated. |
| Strong CYP2D6 Inhibitor              | Reduce the dose of ARISTADA to the next lower strength. No dosage adjustment is necessary in patients taking 441 mg ARISTADA, if tolerated.  
  *For patients known to be poor metabolizers of CYP2D6:* No dose adjustment required. |
| Both Strong CYP3A4 Inhibitor and Strong CYP2D6 Inhibitor | Avoid use for patients at 662 mg, 882 mg or 1064 mg dose. No dosage adjustment is necessary in patients taking 441 mg ARISTADA, if tolerated. |
| CYP3A4 Inducers                      | No dose adjustment for 662 mg, 882 mg or 1064 mg dose; increase the 441 mg dose to 662 mg. |

* For the 882 mg dose administered every 6 weeks and the 1064 mg dose administered every 2 months, the next lower strength should be 441 mg administered monthly.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
EARLY DOSING GUIDANCE

The recommended ARISTADA dosing interval of 441 mg, 662 mg, and 882 mg monthly; 882 mg every 6 weeks; or 1064 mg every 2 months should be maintained. In the event of early dosing, an ARISTADA injection should not be given earlier than 14 days after the previous injection.35

REINITIATING ARISTADA TREATMENT AFTER MISSING A DOSE

When any dose is missed, administer the next injection of ARISTADA as soon as possible. If the time elapsed since the last ARISTADA injection exceeds the length of time noted below, use the concomitant supplementation with the next ARISTADA injection as recommended below.35

<table>
<thead>
<tr>
<th>DOSE OF LAST ARISTADA INJECTION</th>
<th>LENGTH OF TIME SINCE LAST INJECTION</th>
<th>Supplement with a single dose of ARISTADA INITIO® (aripiprazole lauroxil) or 7 days of oral aripiprazole*</th>
<th>Reinitiate with a single dose of ARISTADA INITIO and a single dose of 30 mg oral aripiprazole or supplement with 21 days of oral aripiprazole*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1064 MG EVERY 2 MONTHS</td>
<td>≤10 weeks</td>
<td>&gt;10 and ≤12 weeks</td>
<td>&gt;12 weeks</td>
</tr>
<tr>
<td>882 MG MONTHLY &amp; EVERY 6 WEEKS</td>
<td>≤8 weeks</td>
<td>&gt;8 and ≤12 weeks</td>
<td>&gt;12 weeks</td>
</tr>
<tr>
<td>662 MG MONTHLY</td>
<td>≤8 weeks</td>
<td>&gt;8 and ≤12 weeks</td>
<td>&gt;12 weeks</td>
</tr>
<tr>
<td>441 MG MONTHLY</td>
<td>≤6 weeks</td>
<td>&gt;6 and ≤7 weeks</td>
<td>&gt;7 weeks</td>
</tr>
</tbody>
</table>

* The patient should supplement with the same dose of oral aripiprazole as when the patient began ARISTADA.35

When any dose is missed, the next injection of ARISTADA needs to be administered as soon as possible.35

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
ARISTADA

How supplied
ARISTADA® (aripiprazole lauroxil) extended-release injectable suspension is available in dose strengths of 441 mg in 1.6 mL, 662 mg in 2.4 mL, 882 mg in 3.2 mL, and 1064 mg in 3.9 mL. The kit contains a 5-mL pre-filled, single use syringe containing ARISTADA sterile aqueous suspension and safety needles.35

• The 441 mg strength kit (NDC 65757-0401-03; light blue label) contains 3 safety needles:
  - a 1-inch (25 mm) 21 gauge needle
  - a 1½-inch (38 mm) 20 gauge needle
  - a 2-inch (50 mm) 20 gauge needle

• The 662 mg strength kit (NDC 65757-0402-03; green label) contains 2 safety needles:
  - a 1½-inch (38 mm) 20 gauge needle
  - a 2-inch (50 mm) 20 gauge needle

• The 882 mg strength kit (NDC 65757-0403-03; burgundy label) contains 2 safety needles:
  - a 1½-inch (38 mm) 20 gauge needle
  - a 2-inch (50 mm) 20 gauge needle

• The 1064 mg strength kit (NDC 65757-0404-03; dark blue label) contains 2 safety needles:
  - a 1½-inch (38 mm) 20 gauge needle
  - a 2-inch (50 mm) 20 gauge needle

Storage
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).35

• Store each product properly per instructions on carton(s)
ORDERING AND PROCUREMENT

Providers have several options for ordering and procuring ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil), depending on their site of care. In general, Alkermes has established an open network for ARISTADA INITIO and/or ARISTADA. The following chart shows some of the wholesalers that can provide distribution support for obtaining ARISTADA INITIO and/or ARISTADA.

<table>
<thead>
<tr>
<th>Wholesaler/Distributor</th>
<th>Phone</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>AmerisourceBergen®</td>
<td>1-844-222-2273</td>
<td><a href="http://www.amerisourcebergen.com">http://www.amerisourcebergen.com</a></td>
</tr>
<tr>
<td>Cardinal Health™</td>
<td>1-800-926-3161</td>
<td><a href="http://www.cardinalhealth.com">http://www.cardinalhealth.com</a></td>
</tr>
<tr>
<td>McKesson</td>
<td>1-885-625-7385</td>
<td><a href="http://www.mckesson.com">http://www.mckesson.com</a></td>
</tr>
</tbody>
</table>

Alkermes, Inc. does not endorse the use of any specific company shown here. This information is provided as a service to our customers.

Product returns and replacements

For product returns, call 1-855-318-4160 or send an email to AlkermesReturns@icsconnect.com. For product replacements, call 1-888-235-8008.
ACCESSING TREATMENT
ARISTADA CARE SUPPORT

Access support
ARISTADA Care Support can provide information, documentation, and reimbursement support one-on-one. Call 1-866-ARISTADA (1-866-274-7823), Monday through Friday, 9 AM to 8 PM EST.

<table>
<thead>
<tr>
<th>ASSESS COVERAGE</th>
<th>ARISTADA Care Support can provide general coverage information for ARISTADA INITIO® (aripiprazole lauroxil) and ARISTADA® (aripiprazole lauroxil) treatment, including prior authorization requirements, in about 15 minutes.</th>
</tr>
</thead>
<tbody>
<tr>
<td>FULL BENEFIT INVESTIGATION</td>
<td>Patient enrollment allows for ARISTADA Care Support to conduct a full benefit investigation and provide a written summary of benefits, usually within 24 hours.</td>
</tr>
<tr>
<td>PRIOR AUTHORIZATION ASSISTANCE</td>
<td>If a prior authorization is needed, ARISTADA Care Support can provide letter of medical necessity templates and authorization forms for ARISTADA INITIO and/or ARISTADA.</td>
</tr>
<tr>
<td>APPEALS ASSISTANCE</td>
<td>If a claim is denied, ARISTADA Care Support can help obtain information regarding the denial of coverage and provide appeal requirements for ARISTADA INITIO and/or ARISTADA.</td>
</tr>
</tbody>
</table>

Online platforms available

**iAssist** provides attachment and direct submission of electronic medical records and electronic prescriptions to:
- Verify patient health plan eligibility in real time
- Electronically submit prior authorization forms (if applicable)
- Complete online enrollment for ARISTADA Care Support services

**CoverMyMeds** offers free electronic prior authorization (ePA) services and ability to:
- Find, complete, and submit prior authorizations to any payer
- Receive electronic determinations
- Create prior authorization renewals

Enroll your patients at aristadacaresupport.com for assistance with coverage investigations and prior authorization requirements.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
ACCESSING TREATMENT, (CONT.)
ARISTADA CARE SUPPORT

Assistance programs

ARISTADA PATIENT ASSISTANCE PROGRAM
The ARISTADA Patient Assistance Program provides uninsured patients who meet program eligibility access to ARISTADA INITIO® (aripiprazole lauroxil) and ARISTADA® (aripiprazole lauroxil) treatment at no charge for up to 12 months.*

Definition of uninsured patients
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.

Eligibility criteria
• Patients must provide proof of household size and annual gross income and certify accuracy
• Prescription must be authorized by a US-licensed healthcare provider
• Shipment must be delivered to a licensed healthcare provider at a location within the 50 states (excluding PR and US Territories)
• Patients must be prescribed ARISTADA INITIO and ARISTADA for an on-label indication

Uninsured patients may have access to ARISTADA INITIO and ARISTADA treatment at no charge.

Eligible patients may have a co-pay cost as low as $10.

CO-PAY SAVINGS PROGRAM†
• Reduce patients’ out-of-pocket costs
• Patients with commercial insurance may be eligible to receive assistance to reduce their co-pay to as low as $10 per prescription.

Savings will occur at the point of purchase and are not dependent on any income criteria

Enroll your patients at aristadacaresupport.com for assistance with coverage and prior authorization requirements.

* The ARISTADA Patient Assistance Program does not cover or provide support for supplies, procedures, or any physician-related services associated with ARISTADA therapy.
† Patients are ineligible for the co-pay program if they are under the age of 18 and/or if they are eligible to purchase their prescription with benefits from Medicare, including Medicare Part D or Medicare Advantage plans; Medicaid, including Medicaid Managed Care or Alternative Benefit Plans (“ABPs”) under the Affordable Care Act; Medigap; Veterans Administration (“VA”); Department of Defense (“DoD”); TriCare®; or any similar state-funded programs such as pharmaceutical assistance programs. Void where prohibited by law, taxed, or restricted. Alkermes, Inc. reserves the right to rescind, revoke, or amend these offers without notice.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
HOSPITAL INPATIENT FREE TRIAL PROGRAM
ARISTADA CARE SUPPORT

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® (aripiprazole lauroxil) and ARISTADA® (aripiprazole lauroxil), 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 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.  
  • The Hospital Inpatient Free Trial Program includes all available strengths for 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 for any patient receiving a free trial unit through this program. For full eligibility terms and restrictions, visit aristadacaressupport.com.

* Available only to pharmacies of inpatient hospitals that are licensed as a hospital and cannot accept PDMA-compliant samples.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
SUPPORTING CONTINUITY OF CARE
ARISTADA CARE SUPPORT

Transition of Care Support Program

ARISTADA Care Support can help your hospitalized patients successfully transition and stay on their HCP-prescribed treatment plan with ARISTADA® (aripiprazole lauroxil) in the outpatient setting.

THE ARISTADA CARE SUPPORT NURSE COORDINATOR TEAM CAN:

| CONNECT | with both inpatient and outpatient staff to assist patients in transitioning from hospital to outpatient setting for their ARISTADA treatment |
| IDENTIFY | alternate sites that can administer ARISTADA for follow-up care |
| SCHEDULE | appointments and provide confirmations for patients if needed |
| REMIND | patients about upcoming appointments, upon request, to help keep them on track with their treatment plan |

Enroll your patients now at aristadacaresupport.com.

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.

This online searchable network database is available through aristadacaresupport.com and specifies what type of services each location will provide.

The ARISTADA Provider Network enables patients to get the continuity of care they need.

HOW TO FIND AN ARISTADA PROVIDER

1. GO ONLINE aristadacaresupport.com/find-provider
2. FIND AN ARISTADA PROVIDER
   Many participants from community clinics and pharmacies opt in to provide services.

JOIN THE ARISTADA PROVIDER NETWORK

If you’d like to be listed as an ARISTADA provider for patients with schizophrenia, you can sign up today at aristadacaresupport.com.

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.

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
INDICATION and IMPORTANT SAFETY INFORMATION for ARISTADA INITIO® (aripiprazole lauroxil) and ARISTADA® (aripiprazole lauroxil) extended-release injectable suspension, for intramuscular use

INDICATION

ARISTADA INITIO, in combination with oral aripiprazole, is indicated for the 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

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 pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available.

Tardive Dyskinesia (TD): The risk of developing TD (a syndrome of abnormal, involuntary movements) and the potential for it to become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic increase. The syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. Prescribing antipsychotics should be consistent with the need to minimize TD. Discontinue ARISTADA if clinically appropriate. TD may remit, partially or completely, if antipsychotic treatment is withdrawn.

Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that include:

- Hyperglycemia/Diabetes Mellitus: Hyperglycemia, in some cases extreme and associated with ketoacidosis, coma, or death, has been reported in patients treated with atypical antipsychotics. There have been reports of hyperglycemia in patients treated with oral aripiprazole. Patients with diabetes should be regularly monitored for worsening of glucose control; those with risk factors for diabetes should undergo baseline and periodic fasting blood glucose testing. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia, including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients require continuation of antidiabetic treatment despite discontinuation of the suspect drug.

- Dyslipidemia: Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.

- Weight Gain: Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Pathological Gambling and Other Compulsive Behaviors: Compulsive or uncontrollable urges to gamble have been reported with use of aripiprazole. Other compulsive urges less frequently reported include sexual urges, shopping, binge eating and other impulsive or compulsive behaviors which may result in harm for the patient and others if not recognized. Closely monitor patients and consider dose reduction or stopping aripiprazole if a patient develops such urges.

(continued on following page)
Orthostatic Hypotension: Aripiprazole may cause orthostatic hypotension which can be associated with dizziness, lightheadedness, and tachycardia. Monitor heart rate and blood pressure, and warn patients with known cardiovascular or cerebrovascular disease and risk of dehydration and syncope.

Falls: Antipsychotics including ARISTADA INITIO and ARISTADA may cause somnolence, postural hypotension or motor and sensory instability which may lead to falls and subsequent injury. Upon initiating treatment and recurrently, complete fall risk assessments as appropriate.

Leukopenia, Neutropenia, and Agranulocytosis: Leukopenia, neutropenia and agranulocytosis have been reported with antipsychotics. Monitor complete blood count in patients with pre-existing low white blood cell count (WBC)/absolute neutrophil count or history of drug-induced leukopenia/neutropenia. Discontinue ARISTADA INITIO and/or ARISTADA at the first sign of a clinically significant decline in WBC and in severely neutropenic patients.

Seizures: Use with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

Potential for Cognitive and Motor Impairment: ARISTADA INITIO and ARISTADA may impair judgment, thinking, or motor skills. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are certain therapy with ARISTADA INITIO and/or ARISTADA does not affect them adversely.

Body Temperature Regulation: Disruption of the body’s ability to reduce core body temperature has been attributed to antipsychotic agents. Advise patients regarding appropriate care in avoiding overheating and dehydration. Appropriate care is advised for patients who may exercise strenuously, may be exposed to extreme heat, receive concomitant medication with anticholinergic activity, or are subject to dehydration.

Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use; use caution in patients at risk for aspiration pneumonia.

Concomitant Medication: ARISTADA INITIO is only available at a single strength as a single-dose pre-filled syringe, so dosage adjustments are not possible. Avoid use in patients who are known 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.
REFERENCES


REFERENCES, (CONT.)


34. ARISTADA INITIO (aripiprazole lauroxil) [prescribing information]. Waltham, MA: Alkermes; 2018.

35. ARISTADA (aripiprazole lauroxil) [prescribing information]. Waltham, MA: Alkermes; 2018.

CMS-1500 CODING EXAMPLE FOR ADMINISTRATION OF ARISTADA INITIO® (aripiprazole lauroxil) ONLY

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ARISTADA INITIO ARIPIPRAZOLE LAUROXIL 675MG IM 65757-0500-03

FORM UB-04 CODING EXAMPLE FOR ADMINISTRATION OF ARISTADA INITIO ONLY

80 REMARKS
ARISTADA INITIO ARIPIPRAZOLE LAUROXIL 675MG IM 65757-0500-03

ARISTADA 675 mg ADMINISTERED ON JULY 1, 2018
(Shown here as July 1, 2018 for example purposes only)

Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.
Please see additional Important Safety Information on pages 73 to 74 and accompanying full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.