ARISTADA INITIO® (aripiprazole lauroxil) and
ARISTADA® (aripiprazole lauroxil)

CODING AND BILLING SUMMARY

Images not to scale.
For illustration purposes only.

For adult patients with schizophrenia

HELP PATIENTS START THEIR LAI TREATMENT COURSE IN A SINGLE DAY[1,2,a]

[a]ARISTADA treatment can also be started with 21 consecutive days of oral aripiprazole with the first ARISTADA injection.[1,2]

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

INDICATION

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

ARISTADA is indicated for the treatment of schizophrenia in adults.

IMPORTANT SAFETY INFORMATION

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ARISTADA INITIO and ARISTADA are not approved for the treatment of patients with dementia-related psychosis.

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

Please see additional Important Safety Information on pages 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

ARISTADA INITIO® aripiprazole lauroxil extended-release injectable suspension 675 mg

ARISTADA® aripiprazole lauroxil extended-release injectable suspension 441 mg | 662 mg | 882 mg | 1064 mg

ARISTADA INITIATION REGIMEN

INITIATION: ARISTADA INITIO® +30 MG ORAL ARIPIPRAZOLE + TREATMENT: ARISTADA

IN 1 DAY[1,2,a]

The ARISTADA® (aripiprazole lauroxil) Initiation Regimen includes a one-time dose of ARISTADA INITIO® (aripiprazole lauroxil), a single dose of 30 mg oral aripiprazole, and any ARISTADA dose[1,2]

Initiate 1 to 2 months of treatment in a single day[1,a,b]

STEP 1

- **1 ARISTADA INITIO dose**
- **A single 30 mg dose of oral aripiprazole**

Images not to scale. For illustration purposes only.

STEP 2

- **Select 1 ARISTADA dose and give on the same day or up to 10 days later, if desired**

Images not to scale. For illustration purposes only.

441 mg
662 mg
882 mg
1064 mg

[a]For additional ARISTADA initiation options, refer to the full Prescribing Information.
[b]The ARISTADA Initiation Regimen includes a one-time dose of ARISTADA INITIO, a single dose of 30 mg oral aripiprazole, and any ARISTADA dose. ARISTADA treatment can also be started with 21 consecutive days of oral aripiprazole with the first ARISTADA injection.[1,2]

Important Dosing and Administration Considerations for ARISTADA INITIO and ARISTADA

- For patients who have never taken aripiprazole, establish tolerability with oral aripiprazole prior to initiating ARISTADA or ARISTADA INITIO[1,2]
- ARISTADA INITIO and ARISTADA are not interchangeable because of differing pharmacokinetic profiles[1]
- ARISTADA INITIO and ARISTADA are only to be administered as an intramuscular injection by a healthcare professional[1,2]
- Initiate ARISTADA with the ARISTADA Initiation Regimen or with 21 consecutive days of oral aripiprazole[1,2]
- ARISTADA INITIO can be administered in the deltoid or gluteal muscle; ARISTADA can be administered in the deltoid (441 mg dose only) or gluteal muscle (all doses); avoid injecting both ARISTADA and ARISTADA INITIO concomitantly into the same deltoid or gluteal muscle[1,2]
  - If desired, you can administer the ARISTADA maintenance dose up to 10 days later, based on the needs of your patient[1,2]
- When any dose of ARISTADA is missed, administer the next injection of ARISTADA as soon as possible[1,2]
- ARISTADA INITIO is only available at a single strength as a single-dose prefilled 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; or antihypertensive drugs, and benzodiazepines[1]
  - Avoid initiating ARISTADA treatment with ARISTADA INITIO in patients requiring dose adjustments[1,2]
- Depending on concomitant medications, dose adjustments may be recommended; refer to Table 4 of the full Prescribing Information for ARISTADA dose adjustments with concomitant CYP450 modulator use[2]
- ARISTADA INITIO is only to be used as a single dose to initiate ARISTADA treatment or as a single dose to reinitiate ARISTADA treatment following a missed dose of ARISTADA; ARISTADA INITIO is not intended for repeat dosing[1]
- Available ARISTADA dosing options include: 441 mg monthly, 662 mg monthly, 882 mg monthly or every 6 weeks, or 1064 mg every 2 months[2]

IMPORTANT SAFETY INFORMATION *(cont'd)*

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 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

ARISTADA INITIO® aripiprazole lauroxil extended-release injectable suspension — 675 mg

ARISTADA® aripiprazole lauroxil extended-release injectable suspension — 441 mg | 662 mg | 882 mg | 1064 mg

Coding and Billing Summary

The information in this summary is provided to help support coding and billing for patients with schizophrenia who are being treated with ARISTADA INITIO® (aripiprazole lauroxil) and/or ARISTADA® (aripiprazole lauroxil).

National Drug Codes (NDCs)

The following NDC codes have been assigned to ARISTADA INITIO and ARISTADA. Coding decisions should be made by the physician based on an independent review of the patient's condition.

NDC for ARISTADA INITIO[1]	
Dosage Strength	**11-digit NDC**
675 mg	65757-0500-03

NDCs for ARISTADA[2]	
Dosage Strength	**11-digit NDC**
441 mg	65757-0401-03
662 mg	65757-0402-03
882 mg	65757-0403-03
1064 mg	65757-0404-03

Healthcare Common Procedure Coding System (HCPCS) Codes

ARISTADA INITIO

ARISTADA INITIO received its own J-code (J1943) effective for dates of service on and after October 1, 2019. The code J1943 may be used when ARISTADA INITIO is being billed under the medical benefit.

HCPCS Code[3]	Description	Settings of Care
J1943	Injection, aripiprazole lauroxil, (ARISTADA INITIO), 1 mg	Most payers and care settings

ARISTADA

ARISTADA received an updated J-Code (J1944) effective for dates of service on and after on October 1, 2019. The code J1944 may be used when ARISTADA is being billed under the medical benefit.

HCPCS Code[3]	Description	Settings of Care
J1944	Injection, aripiprazole lauroxil, (ARISTADA), 1 mg	Most payers and care settings

Please see additional Important Safety Information on pages 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

Summary Information for Outpatient, Physician Office, or CMHC Settings

Summary Information for ARISTADA INITIO® (aripiprazole lauroxil)

Code Set	Code[3]	Description	Settings of Care
HCPCS	J1943	Injection, aripiprazole lauroxil, (ARISTADA INITIO), 1 mg	Most payers and care settings

Procedural Codes for ARISTADA INITIO[4]		
CPT®*	96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular†

Summary Information for ARISTADA® (aripiprazole lauroxil)

Code Set	Code[3]	Description	Settings of Care
HCPCS	J1944	Injection, aripiprazole lauroxil, (ARISTADA), 1 mg	Most payers and care settings

Procedural Codes for ARISTADA[4]		
CPT®*	96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular†

CMHC=Community Mental Health Center
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 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

Shared Summary

Claims submitted for ARISTADA® (aripiprazole lauroxil) and/or ARISTADA INITIO® (aripiprazole lauroxil) should include at least one (1) ICD-10-CM diagnosis code to indicate the patient's condition. Specific diagnosis codes should represent the condition as supported by the patient's medical record. The diagnosis codes listed below may apply for patients for whom ARISTADA and/or ARISTADA INITIO may be appropriate.

ICD-10-CM Diagnosis Code[5,6]	Code Description
F20.0	Paranoid schizophrenia
F20.1	Disorganized schizophrenia
F20.2	Catatonic schizophrenia
F20.3	Undifferentiated schizophrenia
F20.5	Residual schizophrenia
F20.89	Other schizophrenia
F20.9	Unspecified schizophrenia

IMPORTANT SAFETY INFORMATION *(cont'd)*

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. *(continued on the next page)*

Please see additional Important Safety Information on pages 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

Coding for Treatment With ARISTADA INITIO® (aripiprazole lauroxil) and ARISTADA® (aripiprazole lauroxil)

Claim Form 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 CMS-1500 form is the standard paper claim form used to bill most insurance carriers, including Medicare, Medicaid, and commercial carriers when a paper claim is allowed. Data elements in the CMS uniform electronic billing specifications for 837P are consistent with the hard copy data set.[7]

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.[8] Healthcare professionals in an office setting who treat Medicare beneficiaries may use the CMS-1500 form (02/12) for most payers who accept paper claims if a paper claim is necessary.[7]

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.

Recording Drug Administration

- The first ARISTADA injection may be administered on the same day as ARISTADA INITIO or up to 10 days thereafter
- 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
- Subsequent ARISTADA doses may be administered on a monthly, 6 week, or 2 month dose intervals. Please see ARISTADA Prescribing Information for complete information regarding dosing and administration of ARISTADA
- Please see the following sample forms beginning on page 10 for examples based on the administration of the drug

IMPORTANT SAFETY INFORMATION *(cont'd)*

Hyperglycemia/Diabetes Mellitus (cont'd): Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia, including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients require continuation of antidiabetic treatment despite discontinuation of the suspect drug.

- **Dyslipidemia:** Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.
- **Weight Gain:** Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Please see additional Important Safety Information on pages 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

Quick Reference Table for CMS-1500/837P

Field/Category Name[9]	ARISTADA INITIO® (aripiprazole lauroxil) Example*	ARISTADA® (aripiprazole lauroxil) Example*	837P Loop ID, Segment/Data Element[10]	CMS-1500 (02/12) Field Number[9]
Procedures, Services, or Supplies (e.g., NDCs)	**675 mg:** NDC 65757-0500-03	**441 mg:** NDC 65757-0401-03 **662 mg:** NDC 65757-0402-03 **882 mg:** NDC 65757-0403-03 **1064 mg:** NDC 65757-0404-03	Loop 2400/ SV101	Field 24D
Procedures, Services, or Supplies (e.g., CPT® code†)	96372 therapeutic, prophylactic, or diagnostic injection‡ **Note:** *Payer policy may vary on requirements for billing two separate drug injections on the same date. Please review individual payer policy. A modifier may be utilized with the second injection procedure code on the CMS-1500 claim form.*	96372 therapeutic, prophylactic, or diagnostic injection‡ **Note:** *Payer policy may vary on requirements for billing two separate drug injections on the same date. Please review individual payer policy. A modifier may be utilized with the second injection procedure code on the CMS-1500 claim form.*		
Procedures, Services, or Supplies (e.g., HCPCS code)	J1943	J1944		
Units	**675 units for 675 mg**	**441 units for 441 mg** **662 units for 662 mg** **882 units for 882 mg** **1064 units for 1064 mg**	Loop 2400/ SV104	Field 24G
Diagnosis or Nature of Illness or Injury	Input appropriate diagnosis code	Input appropriate diagnosis code	Loop 2300/ HI01-2 to HI12-2	Field 21

CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association.

* 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 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

ARISTADA INITIO® aripiprazole lauroxil extended-release injectable suspension 675 mg + ARISTADA® aripiprazole lauroxil extended-release injectable suspension 441 mg 662 mg 882 mg 1064 mg

Hospital Outpatient or Partial Hospitalization Coding for Treatment With ARISTADA INITIO® (aripiprazole lauroxil) and 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.[11]

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.

Recording Drug Administration

- The first ARISTADA injection may be administered on the same day as ARISTADA INITIO or up to 10 days thereafter
- 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
- Subsequent ARISTADA doses may be administered on monthly, 6 week, or 2 month dose intervals. Please see ARISTADA Prescribing Information for complete information regarding dosing and administration of ARISTADA
- Please see the following sample forms beginning on page 10 for guidance based on the administration of the drug

IMPORTANT SAFETY INFORMATION *(cont'd)*

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

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

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

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

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

Please see additional Important Safety Information on pages 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

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

Field/Category Name[12]	ARISTADA INITIO® (aripiprazole lauroxil) Example	ARISTADA® (aripiprazole lauroxil) Example	837I Loop ID, Segment/ Data Element[12]	UB-04/ CMS-1450[12]
Revenue Code[13]	• 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)	• 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	Field 42
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)	Check with payer (instructions may vary)	Field 43
CPT® Code*	96372 (therapeutic, prophylactic, or diagnostic injection)†	96372 (therapeutic, prophylactic, or diagnostic injection)†	Loop 2400, SV202-2	Field 44
HCPCS Code	J1943 for ARISTADA INITIO	J1944 for ARISTADA		
Service Units	**675 units for 675 mg**	**441 units for 441 mg** **662 units for 662 mg** **882 units for 882 mg** **1064 units for 1064 mg**	Loop 2400, SV205	Field 46
Diagnosis	Input appropriate diagnosis code	Input appropriate diagnosis code	Loop 2300, HI01-2 (HI01-1=BK)	Fields 67A-Q

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.

IMPORTANT SAFETY INFORMATION *(cont'd)*

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.

Please see additional Important Safety Information on pages 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

ARISTADA INITIO® aripiprazole lauroxil extended-release injectable suspension 675 mg

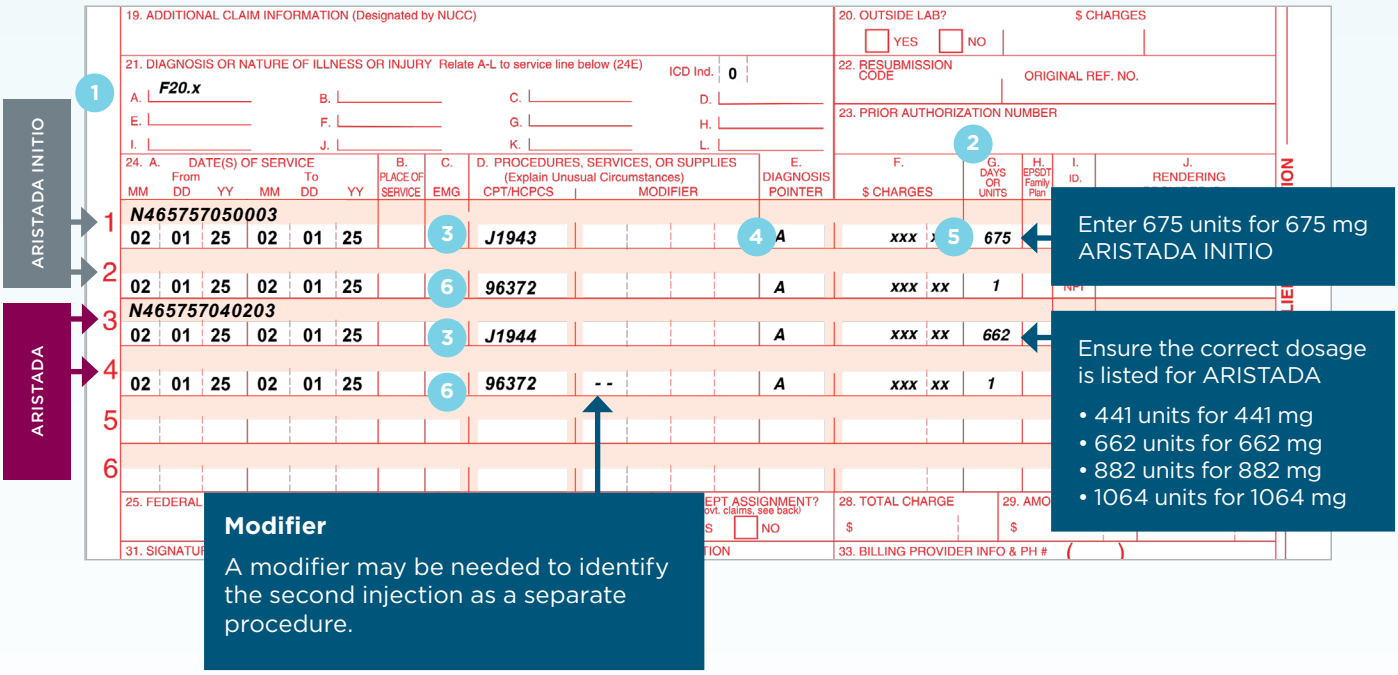
ARISTADA® aripiprazole lauroxil extended-release injectable suspension 441 mg 662 mg 882 mg 1064 mg

Administering ARISTADA INITIO® (aripiprazole lauroxil) and ARISTADA® (aripiprazole lauroxil) on the Same Day

Recording Drug Administration

- ARISTADA INITIO and ARISTADA may be administered on the same day
- Following is an example of billing forms when drug administration happens on the same date. ARISTADA INITIO 675 mg and ARISTADA 662 mg are administered on February 1, 2025

Sample CMS-1500 Claim Form (physician office billing)



ARISTADA INITIO 675 mg and **ARISTADA 662 mg**
Both administered on same date

(Shown here as February 1, 2025 for example purposes only)

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

CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association.

Please see additional Important Safety Information on pages 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

ARISTADA INITIO® aripiprazole lauroxil extended-release injectable suspension 675 mg + ARISTADA® aripiprazole lauroxil extended-release injectable suspension 441 mg 662 mg 882 mg 1064 mg

Completing the CMS-1500 Claim Form

ARISTADA INITIO® (aripiprazole lauroxil) 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, J1943 for ARISTADA INITIO and J1944 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 (one unit of J1943 is equal to 1 mg):
   - 675 units for 675 mg

   b. Report number of units of ARISTADA (one unit of J1944 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 J1944 would be represented as 999 service units and the second line of J1944 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.

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

IMPORTANT SAFETY INFORMATION *(cont'd)*

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.

Please see additional Important Safety Information on pages 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

Administering ARISTADA INITIO® (aripiprazole lauroxil) and ARISTADA® (aripiprazole lauroxil) on the Same Day

Recording Drug Administration

- ARISTADA INITIO and ARISTADA may be administered on the same day
- Following is an example of billing forms when drug administration happens on the same date. ARISTADA INITIO 675 mg and ARISTADA 662 mg are administered on February 1, 2025

Sample CMS-1450 Claim Form (hospital billing)

ARISTADA INITIO

ARISTADA

1 42 REV. CD.	43 DESCRIPTION 2	3 44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS 4
N465757050003				
0636	DRUGS REQUIRING DETAILED INFORMATION	J1943	02 01 25	675
N465757040203				
0636	DRUGS REQUIRING DETAILED INFORMATION	J1944	02 01 25	662
0510	CLINIC VISIT	96372	02 01 25	1

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 675 units for 675 mg ARISTADA INITIO

63 TREATMENT AUTHORIZATION CODES | 64 DOCUMENT CONTROL NUMBER | 65 EMPLOYER NAME

67 DX: F20.x 5 | 68

69 ADMIT DX | 70 PATIENT REASON DX | 71 PPS CODE | 72 ECI | 73

74 PRINCIPAL PROCEDURE CODE DATE | a. OTHER PROCEDURE CODE DATE | b. OTHER PROCEDURE CODE DATE | 75

c. OTHER PROCEDURE CODE DATE | d. OTHER PROCEDURE CODE DATE | e. OTHER PROCEDURE CODE DATE

76 ATTENDING NPI QUAL LAST FIRST

77 OPERATING NPI QUAL LAST FIRST

78 OTHER NPI QUAL LAST FIRST

80 REMARKS | 81CC a b

ARISTADA INITIO 675 mg and **ARISTADA 662 mg**
Both administered on same date

(Shown here as February 1, 2025 for example purposes only)

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

CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association.

Please see additional Important Safety Information on pages 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

ARISTADA INITIO® aripiprazole lauroxil extended-release injectable suspension 675 mg

ARISTADA® aripiprazole lauroxil extended-release injectable suspension 441 mg | 662 mg | 882 mg | 1064 mg

Completing the CMS-1450 Claim Form

ARISTADA INITIO® (aripiprazole lauroxil) 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 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: **J1943** should be used for ARISTADA INITIO
J1944 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)

a. Report number of units of ARISTADA INITIO (one unit of J1943 is equal to 1 mg):
- 675 units for 675 mg

b. Report number of units of ARISTADA (one unit of J1944 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-CM codes for the patient. This field should contain the ICD-10-CM 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.

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

IMPORTANT SAFETY INFORMATION *(cont'd)*

Concomitant Medication (cont'd): 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.)

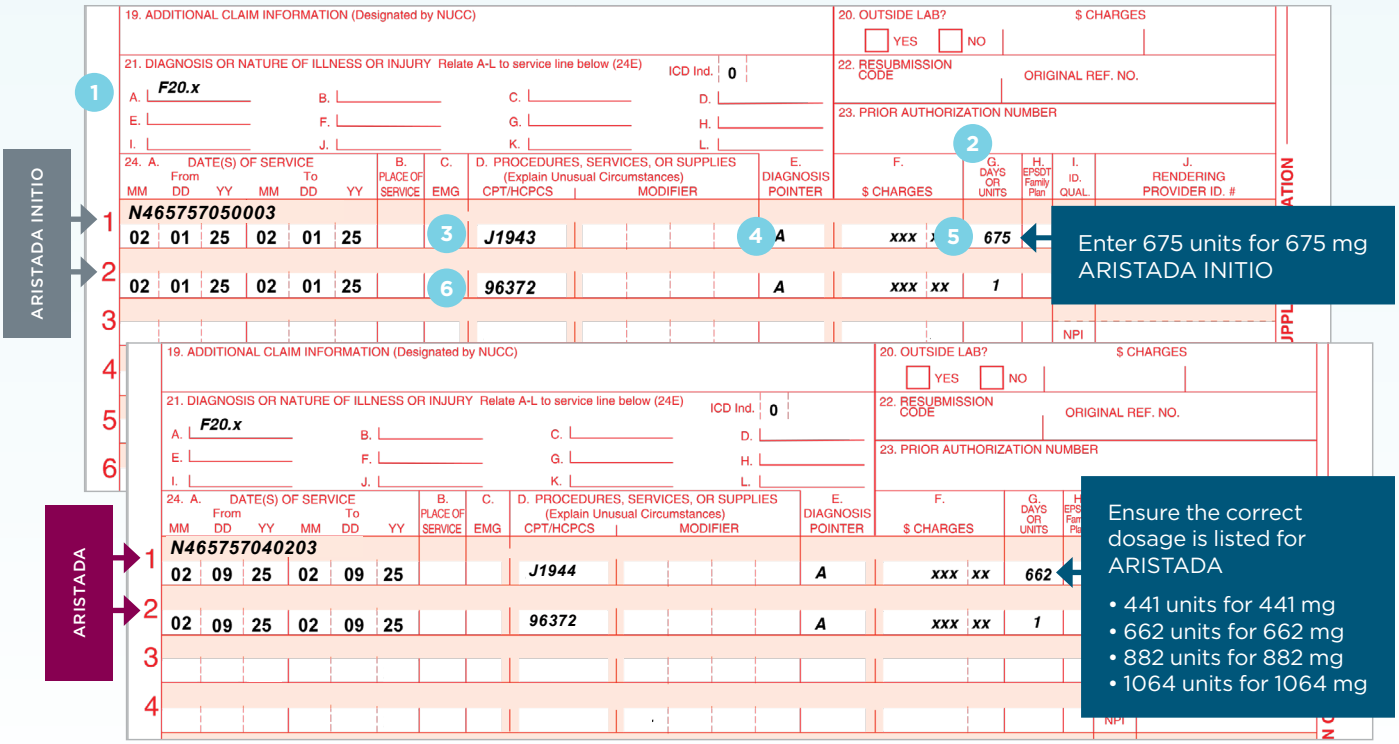
Please see additional Important Safety Information on pages 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

Administering ARISTADA INITIO® (aripiprazole lauroxil) and ARISTADA® (aripiprazole lauroxil) on Different Days

Recording Drug Administration

- The first ARISTADA injection may be administered up to 10 days after ARISTADA INITIO
- Following is an example of billing forms when drug administration happens on different dates. ARISTADA INITIO 675 mg is administered on February 1, 2025 while ARISTADA 662 mg is administered on February 9, 2025

Sample CMS-1500 Claim Form (physician office billing)



ARISTADA INITIO 675 mg
Administered
on February 1, 2025

(Shown here as February 1, 2025
for example purposes only)

ARISTADA 662 mg
Administered
on February 9, 2025

(Shown here as February 9, 2025
for example purposes only)

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

CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association.

Please see additional Important Safety Information on pages 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

ARISTADA INITIO® aripiprazole lauroxil extended-release injectable suspension 675 mg + ARISTADA® aripiprazole lauroxil extended-release injectable suspension 441 mg 662 mg 882 mg 1064 mg

Completing the CMS-1500 Claim Form

ARISTADA INITIO® (aripiprazole lauroxil) Different 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, J1943 for ARISTADA INITIO and J1944 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 (one unit of J1943 is equal to 1 mg):
   - 675 units for 675 mg

   b. Report number of units of ARISTADA (one unit of J1944 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, bill one line of J1944 with 999 service units and bill a second line of J1944 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.

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

IMPORTANT SAFETY INFORMATION *(cont'd)*

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.

Please see additional Important Safety Information on pages 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

Administering ARISTADA INITIO® (aripiprazole lauroxil) and ARISTADA® (aripiprazole lauroxil) on Different Days

Recording Drug Administration

- The first ARISTADA injection may be administered up to 10 days after ARISTADA INITIO
- Following is an example of billing forms when drug administration happens on different dates. ARISTADA INITIO 675 mg is administered on February 1, 2025 while ARISTADA 662 mg is administered on February 9, 2025

Sample CMS-1450 Claim Form (hospital billing)

ARISTADA INITIO

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
N465757050003						
0636	DRUGS REQUIRING DETAILED INFORMATION	J1943	02 01 25	675		
0510	CLINIC VISIT	96372	02 01 25	1		

Enter 675 units for 675 mg ARISTADA INITIO

63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME

67 DX: F20.x

69 ADMIT DX | 70 PATIENT REASON DX | 71 PPS CODE | 72 ECI | 73

ARISTADA

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
N465757040203						
0636	DRUGS REQUIRING DETAILED INFORMATION	J1944	02 09 25	662		
0510	CLINIC VISIT	96372	02 09 25	1		

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

63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMP

67 DX: F20.x

69 ADMIT DX | 70 PATIENT REASON DX | 71 PPS CODE | 72 ECI | 73

ARISTADA INITIO 675 mg
Administered
on February 1, 2025

(Shown here as February 1, 2025 for example purposes only)

ARISTADA 662 mg
Administered
on February 9, 2025

(Shown here as February 9, 2025 for example purposes only)

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

CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association.

Please see additional Important Safety Information on pages 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

ARISTADA INITIO®
aripiprazole lauroxil
extended-release injectable suspension
675 mg

+

ARISTADA®
aripiprazole lauroxil
extended-release injectable suspension
441 mg | 662 mg | 882 mg | 1064 mg

Completing the CMS-1450 Claim Form

ARISTADA INITIO® (aripiprazole lauroxil) 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 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.

a. HCPCS: **J1943** should be used for ARISTADA INITIO

b. HCPCS: **J1944** should be used for ARISTADA

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 (one unit of J1943 is equal to 1 mg):
- 675 units for 675 mg

b. Report number of units of ARISTADA® (aripiprazole lauroxil) (one unit of J1944 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-CM codes for the patient. This field should contain the ICD-10-CM 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.

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

IMPORTANT SAFETY INFORMATION *(cont'd)*

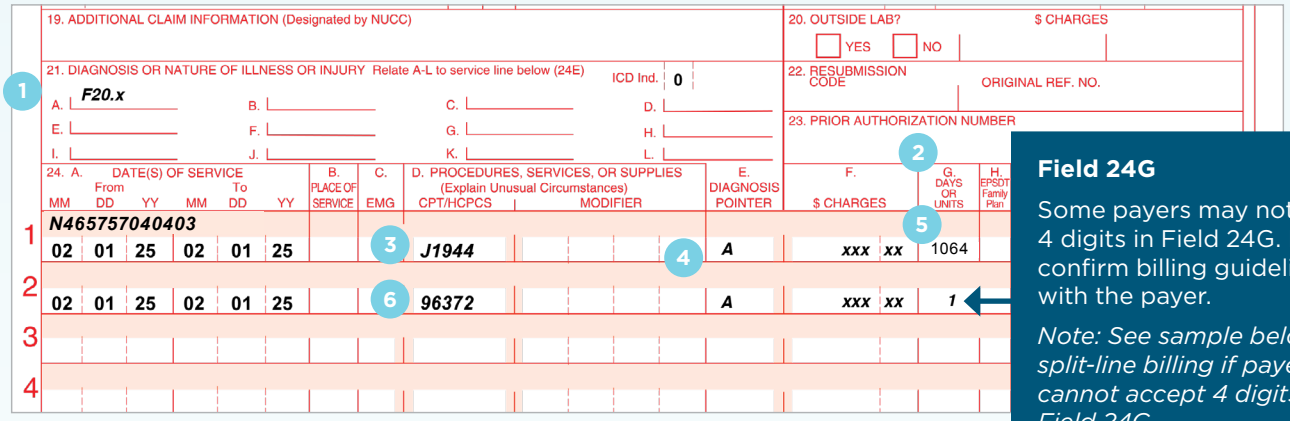
Injection Site Reactions: In pharmacokinetic studies evaluating ARISTADA INITIO, the incidences of injection site reactions with ARISTADA INITIO were similar to the incidence observed with ARISTADA. Injection site reactions were reported by 4%, 5%, and 2% of patients treated with 441 mg ARISTADA (monthly), 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 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

Administering Only ARISTADA® (aripiprazole lauroxil)*

Sample CMS-1500 Claim Form (physician office billing)

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.

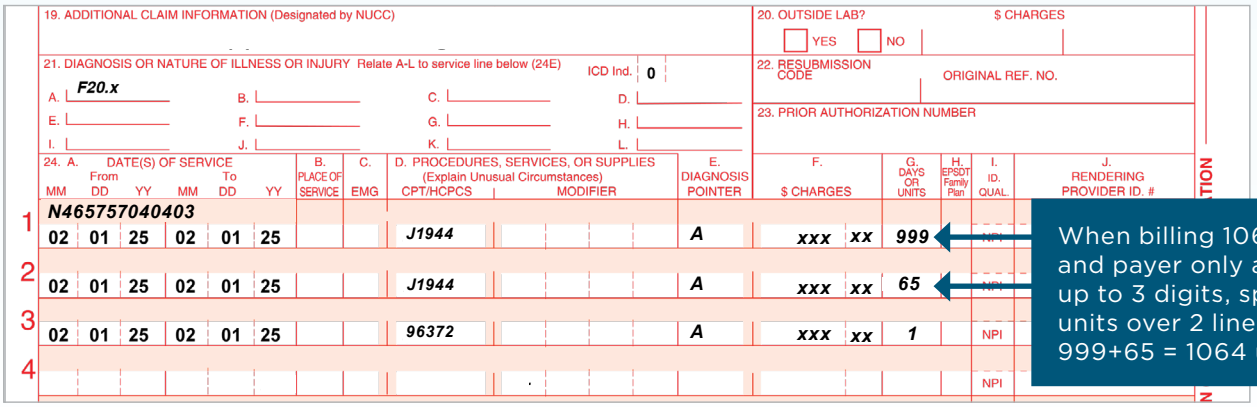


Field 24G

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.



When billing 1064 units and payer only accepts up to 3 digits, split the units over 2 lines: 999+65 = 1064 units

ARISTADA 1064 mg
Administered on February 1, 2025
(Shown here as February 1, 2025 for example purposes only)

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

CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association.

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

Please see additional Important Safety Information on pages 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

ARISTADA INITIO® aripiprazole lauroxil extended-release injectable suspension 675 mg

ARISTADA® aripiprazole lauroxil extended-release injectable suspension 441 mg | 662 mg | 882 mg | 1064 mg

Completing the CMS-1500 Claim Form

Administering only ARISTADA® (aripiprazole lauroxil)

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 J1944.
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 (one unit of J1944 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, bill one line of J1944 with 999 service units and bill a second line of J1944 with 65 service 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*).

CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association.
* ARISTADA is administered as an IM injection only.

IMPORTANT SAFETY INFORMATION *(cont'd)*

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.

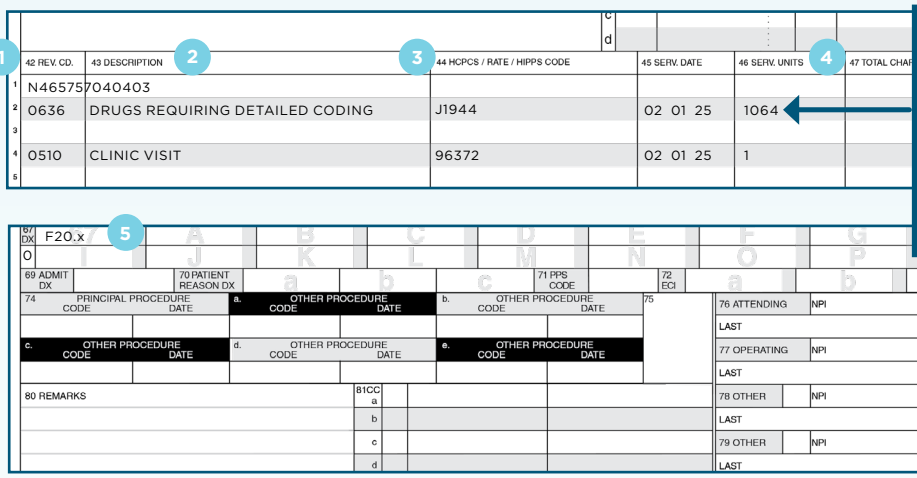
Pregnancy/Nursing: Neonates exposed to antipsychotic drugs, including ARISTADA INITIO and ARISTADA, during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms. Advise patients to notify their healthcare provider of a known or suspected pregnancy. Inform patients 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. Aripiprazole exposure during pregnancy and/or the postpartum period may decrease milk supply. Monitor the breastfed infant for dehydration and lack of appropriate weight gain. 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 additional Important Safety Information on pages 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

Administering Only ARISTADA® (aripiprazole lauroxil)*

Sample CMS-1450 Claim Form (hospital billing)

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.



42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHAR
N46575	7040403				
0636	DRUGS REQUIRING DETAILED CODING	J1944	02 01 25	1064	
0510	CLINIC VISIT	96372	02 01 25	1	

67 DX F20.x

69 ADMIT DX | 70 PATIENT REASON DX | 71 PPS CODE | 72 ECI | 73

74 PRINCIPAL PROCEDURE CODE DATE | a. OTHER PROCEDURE CODE DATE | b. OTHER PROCEDURE CODE DATE | 75

c. OTHER PROCEDURE CODE DATE | d. OTHER PROCEDURE CODE DATE | e. OTHER PROCEDURE CODE DATE

80 REMARKS | 81CC a b c d

76 ATTENDING NPI QUAL LAST FIRST

77 OPERATING NPI QUAL LAST FIRST

78 OTHER NPI QUAL LAST FIRST

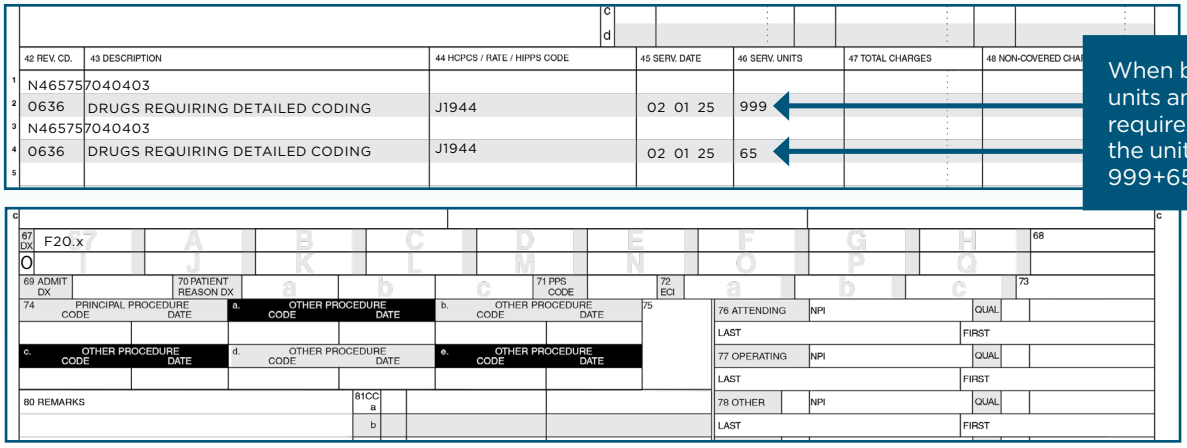
79 OTHER NPI QUAL LAST FIRST

Field 46

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.

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



42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHAR
N46575	7040403					
0636	DRUGS REQUIRING DETAILED CODING	J1944	02 01 25	999		
N46575	7040403					
0636	DRUGS REQUIRING DETAILED CODING	J1944	02 01 25	65		

67 DX F20.x

69 ADMIT DX | 70 PATIENT REASON DX | 71 PPS CODE | 72 ECI | 73

74 PRINCIPAL PROCEDURE CODE DATE | a. OTHER PROCEDURE CODE DATE | b. OTHER PROCEDURE CODE DATE | 75

c. OTHER PROCEDURE CODE DATE | d. OTHER PROCEDURE CODE DATE | e. OTHER PROCEDURE CODE DATE

80 REMARKS | 81CC a b

76 ATTENDING NPI QUAL LAST FIRST

77 OPERATING NPI QUAL LAST FIRST

78 OTHER NPI QUAL LAST FIRST

When billing 1064 units and payer requires 3 digits, split the units over 2 lines: 999+65 = 1064 units

ARISTADA 1064 mg
Administered on February 1, 2025
(Shown here as February 1, 2025 for example purposes only)

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

CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association.
* In conjunction with 21 consecutive days of oral aripiprazole supplementation.

Please see additional Important Safety Information on pages 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

ARISTADA INITIO® aripiprazole lauroxil extended-release injectable suspension
675 mg

ARISTADA® aripiprazole lauroxil extended-release injectable suspension
441 mg | 662 mg | 882 mg | 1064 mg

Completing the CMS-1450 Claim Form

Administering only ARISTADA® (aripiprazole lauroxil)

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 minus any dashes). 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: **J1944** should be used for ARISTADA

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 (one unit of J1944 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-CM codes for the patient. This field should contain the ICD-10-CM 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.

CPT®=Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association.

* ARISTADA is administered as an IM injection only.

Please see additional Important Safety Information on pages 22-23 and 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)

INDICATION

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

ARISTADA is indicated for the treatment of schizophrenia in adults.

IMPORTANT SAFETY INFORMATION

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ARISTADA INITIO and ARISTADA are not approved for the treatment of patients with dementia-related psychosis.

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

Cerebrovascular Adverse Reactions, Including Stroke: Increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack), including fatalities, have been reported in placebo-controlled trials of elderly patients with dementia-related psychosis treated with risperidone, aripiprazole, and olanzapine. ARISTADA INITIO and ARISTADA are not approved for the treatment of patients with dementia-related psychosis.

Potential for Dosing and Medication Errors: Medication errors, including substitution and dispensing errors, between ARISTADA INITIO and ARISTADA could occur. ARISTADA INITIO is intended for single administration in contrast to ARISTADA which is administered monthly, every 6 weeks, or every 8 weeks. Do not substitute ARISTADA INITIO for ARISTADA because of differing pharmacokinetic profiles.

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

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.

INDICATION and IMPORTANT SAFETY INFORMATION for ARISTADA INITIO® and ARISTADA® (cont'd)

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: Neonates exposed to antipsychotic drugs, including ARISTADA INITIO and ARISTADA, during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms. 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. Aripiprazole exposure during pregnancy and/or the postpartum period may decrease milk supply. Monitor the breastfed infant for dehydration and lack of appropriate weight gain. 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.

To report SUSPECTED ADVERSE REACTIONS, contact Alkermes at 1-866-274-7823 or FDA at 1-800-FDA-1088 or https://www.fda.gov/medwatch.

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

References: **1.** ARISTADA INITIO. Package insert. Alkermes, Inc. **2.** ARISTADA. Package insert. Alkermes, Inc. **3.** Centers for Medicare & Medicaid Services. HCPCS Quarterly Update. April 2022 Alpha-Numeric HCPCS File. https://www.cms.gov/files/zip/april-2022-alpha-numeric-hcpcs-file.zip. Accessed February 19, 2025. **4.** *CPT® 2022 Professional Edition: Current Procedural Terminology.* Atlanta, GA: American Medical Association; 2021. **5.** American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition. Arlington, VA: American Psychiatric Association; 2013. **6.** 2015 ICD-10-CM *Complete Draft Code Set: Clinical Modification*. Salt Lake City, UT: American Academy of Professional Coders; 2014. **7.** Centers for Medicare & Medicaid Services. Medicare Prescription Drug Benefit Manual. Chapter 26 - Completing and Processing Form CMS-1500 Data Set. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf. Accessed February 19, 2025. **8.** Centers for Medicare & Medicaid Services. Medicare Billing: 837P and Form CMS-1500. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf. Accessed February 19, 2025. **9.** National Uniform Claim Committee. 1500 health insurance claim form reference instruction manual for form version 02/12. July 2021. https://www.nucc.org/images/stories/PDF/1500_claim_form_instruction_manual_2021_07-v9.pdf. Accessed February 19, 2025. **10.** Palmetto GBA. ASC 837 v5010 to CMS-1500 Crosswalk. http://www.palmettogba.com/Palmetto/Providers.Nsf/files/CMS1500_837v5010_Crosswalk.pdf/$File/CMS1500_837v5010_Crosswalk.pdf. Accessed February 19, 2025. **11.** Centers for Medicare & Medicaid Services. Medicare Prescription Drug Benefit Manual. Chapter 25 - Completing and Processing the Form. CMS-1450 Data Set. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf. Accessed February 19, 2025. **12.** Palmetto GBA. ASC 837I version 5010A2 Institutional Health Care Claim to the CMS-1450 Claim Form Crosswalk. http://www.palmettogba.com/Palmetto/Providers.Nsf/files/EDI_837I_v5010A2_crosswalk.pdf/$File/EDI_837I_v5010A2_crosswalk.pdf. Accessed February 19, 2025. **13.** Centers for Medicare & Medicaid Services. Revised Revenue Code-to-Cost-Center Crosswalk. https://www.cms.gov/apps/aha/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1613-FC-rev-code-to-cost-center-crosswalks.zip. Accessed February 19, 2025.

ARISTADA INITIO® aripiprazole lauroxil extended-release injectable suspension 675 mg

ARISTADA® aripiprazole lauroxil extended-release injectable suspension 441 mg 662 mg 882 mg 1064 mg

ARISTADA® Care Support

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

ACCESS SERVICES	Reimbursement support and financial assistance programs to help patients access treatment.
HOSPITAL SERVICES	A program to help hospitalized patients trial ARISTADA INITIO and ARISTADA in the hospital. A program to help patients secure potential sites and providers for follow-up care.
PRODUCT SUPPORT	Samples, ordering information, and answers to questions about ARISTADA INITIO and ARISTADA.
PATIENT SUPPORT	Educational material and injection provider locator are available for patients and caregivers who need them.

ARISTADA® aripiprazole lauroxil
CARE SUPPORT

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

Please see additional Important Safety Information on pages 22-23 and full Prescribing Information, including Boxed Warning, for ARISTADA INITIO and ARISTADA.

Alkermes®