Aripiprazole lauroxil (Aristada Initio®, Aristada®)	**Place of Service** **Office Administration** **Home Infusion Administration** **Outpatient Facility Administration** **Infusion Center Administration** **HCPCS** **J1943** per 1 mg (Aristada initio) **J1944** per 1 mg (Aristada)

Condition listed in policy (*see criteria for details*)

- Schizophrenia

AHFS therapeutic class: Atypical Antipsychotic

Mechanism of action: Efficacy of aripiprazole may be mediated through a combination of partial agonist activity at D2 and 5-HT1A receptors and antagonist activity at 5-HT2A receptors.

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Aristada Initio® (aripiprazole lauroxil) and Aristada® (aripiprazole lauroxil) for conditions NOT LISTED in section 3 must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Diagnoses other than schizophrenia

- Regimen is a continuation of inpatient hospital therapy.

Covered Doses
Aristada ONLY:
441 mg, 662 mg or 882 mg IM monthly OR
882 mg IM every 6 weeks OR
1064 mg IM every 2 months

Coverage Period
Indefinite

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Aristada Initio® (aripiprazole lauroxil) and Aristada® (aripiprazole lauroxil) and for conditions NOT LISTED in section 3 must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Schizophrenia

Covered Doses

Aristada Initio:
675 mg (This can be given as ONE dose with the first Aristada injection)

Aristada:
441 mg, 662 mg or 882 mg IM monthly OR
882 mg IM every 6 weeks OR
1064 mg IM every 2 months

ICD-10:
F20.0-F29

(4) This Medication is NOT medically necessary for the following condition(s):

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
Aristada Initio: 675 mg (single-use pre-filled syringe, extended-release injectable suspension)
Aristada: 441 mg, 662 mg, 882 mg, or 1064 mg (single-use pre-filled syringe, extended-release injectable suspension)

(6) References

- Aristada® (aripiprazole lauroxil) [Prescribing information]. Waltham, MA: Alkermes, Inc.: 1/2021.
- Aristada Initio® (aripiprazole lauroxil) [Prescribing information]. Waltham, MA: Alkermes, Inc.: 1/2021.
- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Keepers GA, Fochtmann LJ, Anzia JM, Benjamin S, Lyness JM, Mojtabai R, Servis M, Walaszek A, Buckley P, Lenzenweger MF, Young AS, Degenhardt A, Hong SH; (Systematic Review). The American Psychiatric Association Practice Guideline for the Treatment of Patients With Schizophrenia. Am J Psychiatry. 2020 Sep 1;177(9):868-872. https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890424841
- McClellan J, Stock S, American Academy of Child and Adolescent Psychiatry (AACAP) Committee on Quality Issues (CQI). Practice Parameter for the Assessment and Treatment of Children and Adolescents With Schizophrenia. J Am Acad Child Adolescent Psychiatry 2013;52:976-90.

(7) Policy Update

Date of last revision: 2Q2021
Date of next review: 1Q2022
Changes from previous policy version:
- No clinical change to policy following revision.