

Medical Drug Clinical Criteria

Subject:	Aristada Initio (aripiprazole lauroxil)		
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Table of Contents

Overview	Coding	References
Clinical criteria	Document history	

Overview

This document addresses the use of long-acting injectable atypical antipsychotic agent Aristada Initio.

Long-acting injectable antipsychotic agents provide for the ability to dose less frequently and may improve adherence to therapy. Tolerability to the oral counterpart is a requirement for the use of the long-acting atypical injections.

Aristada Initio is approved to treat the following indications in individuals 18 years of age and older: schizophrenia (all agents).

Aristada Initio is unique in that it is an IM injection of aripiprazole lauroxil indicated for the initiation or re-initiation of Aristada IM therapy in the treatment of schizophrenia. Aristada Initio allows for transition to injectable Aristada without the need for oral supplementation. While Aristada requires oral aripiprazole supplementation for 21 days, Aristada Initio plus a single oral dose of aripiprazole 30 mg allows for immediate use of Aristada.

Long acting injectable antipsychotic agents have black box warnings regarding the use of these agents in the treatment of psychosis in the elderly. Elderly patients with dementia-related psychosis are at an increased risk of death. Antipsychotic agents are not approved for treatment of dementia related psychosis.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Aristada Initio (aripiprazole lauroxil) extended-release injectable suspension

Requests for Aristada Initio (aripiprazole lauroxil) extended-release injectable suspension may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has a diagnosis of schizophrenia; **AND**
- III. Individual has established tolerability with oral aripiprazole; **AND**
- IV. Individual is initiating or re-initiating therapy with Aristada; **AND**
- V. Individual will use in conjunction with first Aristada (aripiprazole lauroxil) injection (Note: first Aristada injection may be administered on the same day as Aristada Initio or up to 10 days thereafter); **AND**
- VI. Individual will use in conjunction with one 30 mg dose of oral aripiprazole for the following regimens:
 - A. Individual is initiating therapy with Aristada; **OR**
 - B. Individual is re-initiating therapy with Aristada after greater than 7 weeks since last Aristada 441 mg injection or greater than 12 weeks after all other strengths of Aristada.

Requests for Aristada Initio (aripiprazole lauroxil) extended-release injectable suspension may not be approved for the following criteria:

- I. Individual is using for repeat Aristada dosing; **OR**
- II. Individual has not established tolerability to oral aripiprazole.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J1943 Injection, aripiprazole lauroxil, (Aristada Initio), 1 mg

ICD-10 Diagnosis

F20.0-F20.9 Schizophrenia

Document History

Revised: 02/21/2025

Document History:

- 02/21/2025 – Annual Review: No changes. Coding Reviewed: Updated description for HCPCS J1943.
- 02/24/2023 – Annual Review: No changes. Coding Reviewed: No changes.
- 02/25/2022 – Annual Review: No changes. Coding reviewed: No changes.
- 02/19/2021 – Annual Review: Minor wording updates. Coding Reviewed: No changes.
- 02/21/2020 – Annual Review: No changes. Coding reviewed: No changes
- 9/23/2019- Coding Reviewed: Add HCPCS code J1943 Effective 10/1/19, Removed HCPCS C9036, Removed Aristada Initio from J3490.
- 01/22/2019 –Updated Aristada Initio clinical criteria to include age per label. Coding updates: added C9035 and J3490 for Aristada Initio and dx: F20.0-F20.9 for schizophrenia.
- 08/17/2018 –Select Review: Add new PA and QL for Aristada Initio.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 3, 2025.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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