

Effective Date: 2/2020
Reviewed: 11/2019, 08/2020, 3/2021, 2/2022, 2/2023, 2/2024
Scope: Medicaid

**ABILIFY MAINTENA (aripiprazole extended-release injectable suspension)**  
**ARISTADA (aripiprazole lauroxil extended-release injectable suspension)**  
**ARISTADA INITIO (aripiprazole lauroxil extended-release injectable suspension)**

**POLICY**

**I. INDICATIONS**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

**Abilify Maintena**

Abilify Maintena is indicated for the treatment of schizophrenia in adults and maintenance monotherapy treatment of bipolar I disorder in adults.

**Aristada**

Aristada is indicated for treatment of schizophrenia.

**Aristada Initio**

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

All other indications are considered experimental/investigational and are not a covered benefit.

**II. CRITERIA FOR APPROVAL**

An authorization may be granted when the following criteria (A) and (B) are met:

- A. Tolerability with oral aripiprazole has been established
- B. The requested drug is being prescribed for the treatment of schizophrenia

**OR**

Abilify Maintena is being prescribed for maintenance monotherapy treatment of bipolar I disorder

**III. COVERAGE DURATION**

- 1. Abilify Maintena – 12 months
- 2. Aristada – 12 months
- 3. Aristada Initio – one dose for up to 2 months in addition to approval of Aristada for 12 months

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#### IV. REFERENCES

1. Abilify Maintena [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; February 2023. Accessed February 2024
2. Aristada [package insert]. Waltham, MA: Alkermes, Inc.; December 2023. Accessed February 2024.
3. Aristada Initio [package insert]. Waltham, MA: Alkermes, Inc.; December 2023. Accessed February 2024.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed September 2018.
5. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed September 2018.
6. American Psychiatric Association. Practice guideline for the treatment of patients with schizophrenia, 2<sup>nd</sup> edition. 2010. Available at: [http://psychiatryonline.org/pb/assets/raw/sitewide/practice\\_guidelines/guidelines/schizophrenia.pdf](http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf). Accessed September 2018.