

Effective Date: 2/2020
Reviewed: 11/2019
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

IV. REFERENCES

- 1. Abilify Maintena [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; July 2018.
- 2. Aristada [package insert]. Waltham, MA: Alkermes, Inc.; January 2018.

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3. Aristada Initio [package insert]. Waltham, MA: Alkermes, Inc.; June 2018.
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, 2nd edition. 2010. Available at: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf. Accessed September 2018.