

Effective Date: 2/2020
Reviewed: 11/2019, 08/2020, 3/2021, 2/2022, 2/2023, 2/2024, 11/2024, 2/2025, 3/2026
Scope: Medicaid

ABILIFY ASIMTUFII (aripiprazole extended-release injectable suspension)
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 Asimtufii

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

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

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III. COVERAGE DURATION

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

IV. REFERENCES

1. Abilify Asimtufii [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; April 2025. Accessed February 2026.
2. Abilify Maintena [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; April 2025. Accessed February 2026.
3. Aristada [package insert]. Waltham, MA: Alkermes, Inc.; January 2025. Accessed February 2026.
4. Aristada Initio [package insert]. Waltham, MA: Alkermes, Inc.; January 2025. Accessed February 2026.
5. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed September 2018.
6. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed November 2024.
7. 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 November 2024.