

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2159-8
Program	Prior Authorization/Medical Necessity
Medication	Abilify MyCite® (aripiprazole tablet with sensor)*
P&T Approval Date	1/2019, 3/2019, 4/2019, 4/2020, 6/2021, 6/2022, 7/2023, 7/2024
Effective Date	10/1/2024

1. Background:

Abilify MyCite (aripiprazole tablet with sensor)* is a drug-device combination product comprised of aripiprazole tablets embedded with a sensor intended to track drug ingestion. Abilify MyCite is indicated for the treatment of schizophrenia, bipolar I disorder, and as adjunctive treatment for major depressive disorder. Abilify MyCite has not been shown to improve patient adherence and should not be used to track real-time ingestion during an emergency as the detection may be delayed or may not occur.

2. Coverage Criteria:

<p>A. <u>Initial Therapy</u></p> <p>1. Abilify MyCite* will be approved based on all the following criteria:</p> <p>a. Diagnosis of one of the following:</p> <ul style="list-style-type: none"> (1) schizophrenia (2) bipolar I disorder (3) major depressive disorder (4) autistic disorder (5) Tourette’s disorder <p style="text-align: center;">-AND-</p> <p>b. Submission of medical records documenting the patient is currently prescribed aripiprazole and tolerates the medication.</p> <p style="text-align: center;">-AND-</p> <p>c. Submission of medical records documenting the patient’s adherence to aripiprazole is less than 80% within the past 6 months (medication adherence percentage is defined as the number of pills absent in a given time period divided by the number of pills prescribed during that same time, multiplied by 100).</p> <p style="text-align: center;">-AND-</p> <p>d. All of the following strategies (if applicable to the patient) to improve patient adherence have been tried without success:</p>
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- (1) Utilization of a pill box.
- (2) Utilization of a smart phone reminder (e.g. alarm, application, or text reminder).
- (3) Involving family members or friends to assist.
- (4) Coordinating timing of dose to coincide with dosing of another daily medication.

-AND-

- e. Submission of medical records documenting patient has experienced life-threatening or potentially life-threatening symptoms, or has experienced a severe worsening of symptoms leading to a hospitalization which was attributed to the lack of adherence to aripiprazole.

-AND-

- f. History of failure, contraindication, or intolerance to **one** long-acting injectable antipsychotic (e.g. Abilify Maintena, Risperdal Consta, Invega Trinza)

-AND-

- g. Prescriber acknowledges that Abilify MyCite has not been shown to improve patient adherence and attests that Abilify MyCite is medically necessary for the patient to maintain compliance, avoid life-threatening worsening of symptoms, and reduce healthcare resources utilized due to lack of adherence.

-AND-

- h. Prescriber agrees to track and document adherence of Abilify MyCite through software provided by the manufacturer.

Authorization will be issued for 12 months

B. Reauthorization

1. **Abilify MyCite** will be approved based on **both** of the following criteria:

- a. Documentation that patient is clinically stable on Abilify MyCite.

-AND-

- b. Submission of medical records documenting that the use of Abilify MyCite has increased adherence to 80% or more.

-AND-

- c. Prescriber attests that the patient requires the continued use of Abilify MyCite to remain adherent.

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

*Abilify MyCite is typically excluded from coverage.

4. References:

1. Abilify MyCite [package insert]. Rockville, MD: Otsuka Pharmaceuticals, Inc; February 2023.
2. Levenson, JL. (2020). Psychological factors affecting other medical conditions: Management. D. Solomon (Ed.), UpToDate. Retrieved June 3, 2024.
3. Cramer, JA et al. Medication Compliance and Persistence: Terminology and Definitions. Value in Health, January 2008; 11(1):44-47.
4. Brown, MT at al. Mediation Adherence: WHO Cares? May Clin Proc. April 2011; 86(4):304-314.

Program	Prior Authorization/Medical Necessity – Abilify MyCite (aripiprazole tablet with sensor)
Change Control	
1/2019	New program.
3/2019	Added diagnosis requirement.
4/2019	Added step through long-acting injectables.
4/2020	Changed initial review authorization duration to 12 months. Updated references.
6/2021	Annual review. Updated references.
6/2022	Annual review. Updated references.
7/2023	Annual review. Updated references.
7/2024	Annual review. Updated references.