ABILIFY MYCITE® (aripiprazole tablets with sensor)
MEDICAID MEDICAL NECESSITY REVIEW
Policy Number: C18385-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DUE BY OR BEFORE
04/23/2020	12/16/2020	1/26/2022
HCPCS CODING	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
NA	RxPA	Q1 2021 20210127C18385-A

PRODUCTS AFFECTED:
Abilify MyCite Kit (aripiprazole with biosensor)

DRUG CLASS:
Atypical Antipsychotics

ROUTE OF ADMINISTRATION:
Oral

PLACE OF SERVICE:
Retail Pharmacy

AVAILABLE DOSAGE FORMS:
Tablets with sensor: 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg

FDA-APPROVED USES:
ABILIFY MYCITE is indicated for:

- Treatment of **adults** with schizophrenia.
- Treatment of bipolar I disorder: Acute treatment of **adults** with manic and mixed episodes as monotherapy and as adjunct to lithium or valproate. Maintenance treatment of **adults** as monotherapy and as adjunct to lithium or valproate.
- Adjunctive treatment of **adults** with major depressive disorder (MDD)

Limitations of Use: The ability of ABILIFY MYCITE to improve patient compliance or modify aripiprazole dosage has not been established. The use of ABILIFY MYCITE to track drug ingestion in "real-time" or during an emergency is not recommended because detection may be delayed or not occur.
Abilify MyCite is a drug-device combination product comprised of aripiprazole tablets embedded with an Ingestible Event Marker (IEM) sensor intended to track drug ingestion.

COMPENDIAL APPROVED OFF-LABELED USES:
None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS:
schizophrenia, bipolar I disorder, major depressive disorder (MDD)

REQUIRED MEDICAL INFORMATION:
A. FOR ALL INDICATIONS:
1. The member is using the requested drug for an FDA-Approved indication
AND
2. (a) The member's medication history includes use of all preferred generic formulary oral atypical antipsychotic agents with matching indication
OR
(b) documented intolerance, FDA labeled contraindication, or hypersensitivity to all preferred generic formulary oral atypical antipsychotic agents with matching indication
AND
3. (a) The member has failed, has a contraindication, or is intolerant to ALL preferred long-acting injectable antipsychotics with matching indication
OR
(b) Documentation that the patient is using the requested agent AND is at risk if therapy is changed OR has recently (within 48 hours) been discharged on the requested agent
AND
4. Prescriber attestation that the member is able to swallow tablets whole and will not need to divide, crush, or chew tablets
AND
5. Prescriber attestation that the member is capable and has agreed to wear the Abilify MyCite weekly patch while on this medication
AND
6. The member's specific smartphone is compatible with the Abilify MyCite application, the member is comfortable and willing to use smartphones and applications, and the member has access to a reliable internet connection
AND
7. Documentation that Abilify MyCite is medically necessary as evidenced by:
    a. The member is currently prescribed oral aripiprazole and is tolerating the medication
    AND
    b. The members adherence to aripiprazole is less than 80% within the past 3 months (medication adherence 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)
    AND
    c. The member has tried ALL of the following adherence strategies: utilization of a pill box, utilization of a smartphone reminder (alarm, application, or text reminder), involving family members or friends to assist, and coordinating timing of medication of dose to coincide with dosing of another maintenance medication
    AND
    d. The member has experienced life-threatening symptoms, or has experienced a severe worsening of the disease leading to a hospitalization due to lack of adherence to aripiprazole
AND
8. Prescriber attestation that patient has agreed to provide the prescriber or prescriber agent access to tracking and documenting the member's adherence through Abilify MyCite Dashboard.
AND
9. Prescriber attestation that the ability of Abilify MyCite to improve patient compliance and have a positive impact on health outcomes has not been established and that Abilify MyCite

is medically necessary for the member to avoid life-threatening worsening of symptoms due to lack of adherence.

DURATION OF APPROVAL:
Initial authorization: 3 months, Continuation of Therapy: 3 months

QUANTITY:
Maximum of 30mg per day, 30 days per fill

PRESCRIBER REQUIREMENTS:
None

AGE RESTRICTIONS:
18 years of age and older

CONTINUATION OF THERAPY:
A. FOR ALL INDICATIONS:
1. Documentation of target symptom improvement
AND
2. Documentation that Abilify MyCite has increased adherence to greater than 80%
AND
3. Documentation of no intolerable adverse effects or drug toxicity
AND
4. Documentation in provider progress notes that the prescriber has continuously been monitoring the patient's adherence through the Abilify MyCite dashboard
AND
5. Documentation in provider progress notes that the member has continuously been monitoring their own adherence through the Abilify MyCite smartphone application
AND
6. Documentation in provider progress notes of member's treatment plan that contains either plan for discontinuation or rationale for continued use (with monitoring for tardive dyskinesia) AND that attests that Abilify MyCite continues to be medically necessary and that the member continues to be incapable of maintaining adherence without the Abilify MyCite System

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of atypical antipsychotics are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Antipsychotics are NOT covered for members with use of more than one antipsychotic, unless cross titration is needed for up to 60 days, unless prescriber can provide documentation that that the first agent is titrated to highest possible dose, before adding on another agent for unsolved symptoms.

<u>BLACK BOX WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS and SUICIDAL THOUGHTS AND BEHAVIORS</u>

Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies. The safety and efficacy of Abilify MyCite have not been established in pediatric patients. This drug will not be approved for pediatric patients.

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ABILIFY MYCITE is not approved for the treatment of patients with dementia-related psychosis. The safety and effectiveness of ABILIFY MYCITE have not been established in pediatric patients

OTHER SPECIAL CONSIDERATIONS:
Limitations of Use: The ability of ABILIFY MYCITE to improve patient compliance or modify aripiprazole dosage has not been established. The use of ABILIFY MYCITE to track drug ingestion in “real-time” or during an emergency is not recommended because detection may be delayed or not occur

BACKGROUND:
The ability of ABILIFY MYCITE to improve patient compliance or modify aripiprazole dosage has not been established. The use of ABILIFY MYCITE to track drug ingestion in “real-time” or during an emergency is not recommended because detection may be delayed or not occur.
Abilify MyCite is intended to track if the medication has been taken. The Abilify MyCite system includes aripiprazole tablets embedded with an IEM sensor, a MyCite patch (wearable sensor), MyCite smartphone application to display information for the patient, and a web-based portal for healthcare providers and caregivers.
— The IEM sensor is the size of a grain of sand and is made up of ingredients found in food. The IEM sensor activates when in contact with stomach fluid and communicates tothe MyCite patch. The IEM sensor is then digested and eliminated from the body.
— The MyCite patch detects and records the date and time of the tablet ingestion and certain physiological data, such as activity level, and communicates this to the MyCite smartphone application.
— Web-based dashboards are provided to healthcare providers and caregivers. With patient consent, select members of the family and care team may also access information. The approval of Abilify MyCite was based, in part, on the clinical trial data and experience of oral Abilify. However, the ability of Abilify MyCite to improve patient compliance or modify aripiprazole dosage has not been established.
Similar to Abilify, Abilify MyCite carries a boxed warning regarding increased mortality in elderly patients with dementia-related psychosis and suicidal thoughts and behaviors.
— Skin irritation at the site of the MyCite patch placement may occur in some patients.
— It can take 30 minutes to 2 hours to detect ingestion of the tablet. Sometimes the system maynot detect that the medication has been taken. If this occurs, the dosage should not be repeated.

APPENDIX:
None

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

REFERENCES

1. Abilify Mycite (aripiprazole) [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical; December 2020.
2. FDA approves pill with sensor that digitally tracks if patients have ingested their medication [news release]. FDA; November 2017. URL: https://www.fda.gov/news-events/press-announcements/fda-approves-pill-sensor-digitally-tracks-if-patients-have-ingested-their-medication
3. American Diabetes Association, American Psychiatric Association, American Association of Clinical Endocrinologists, et al. Consensus development of conference on antipsychotic drugs and obesity and diabetes. Diabetes Care. 2004 Feb;65(2):267-72
4. Lehman AF, Lieberman JA, Dixon LB, et al. Practice guidelines for the treatment of patients with schizophrenia, second edition. Am J Psychiatry. 2004 Feb;161(2 Suppl):1-56
5. Hirschfeld RMA, Bowden CL, Gitlin MJ, et al. Practice guideline for the treatment of patients with bipolar disorder, second edition. Arlington, VA: American Psychiatric Association; April 2002. Available online at http://www.psychiatryonline.org/guidelines