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Policy Number: C15913-A

Abilify MyCite Kit (aripiprazole tablets with sensor) NC

PRODUCTS AFFECTED

Abilify MyCite Kit (aripiprazole tablets with sensor)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

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.

DIAGNOSIS:
Schizophrenia, Bipolar I disorder, Major depressive disorder (MDD)

REQUIRED MEDICAL INFORMATION:
All uses of Abilify MyCite Kit (aripiprazole tablets with sensor) are considered not medically necessary in accordance to this policy as improvement in patient compliance or modification of aripiprazole dosage has not been established. This coverage policy is subject to change based on research and medical literature, or at the discretion of Molina Healthcare.
Molina Healthcare will be continuing to evaluate and update this policy as relevant clinical evidence becomes available to determine whether Abilify MyCite Kit (aripiprazole tablets with sensor) provides impact on health outcomes or patient management.

CONTINUATION OF THERAPY:
NA

DURATION OF APPROVAL:
NA

PRESCRIBER REQUIREMENTS:
NA

AGE RESTRICTIONS:
NA

QUANTITY:
NA

PLACE OF ADMINISTRATION:
NA

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Quinolinone Derivatives

FDA-APPROVED USES:
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

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Nevada (Source: Nevada Legislature)
"Chapter 689A of Nevada Revised Statutes (NRS) is hereby amended by adding thereto a new section to read as follows:

1. A policy of health insurance which provides coverage for prescription drugs must not require an insured to submit to a step therapy protocol before covering a drug approved by the Food and Drug Administration that is prescribed to treat a psychiatric condition of the insured, if:
    a. The drug has been approved by the Food and Drug Administration with indications for the psychiatric

condition of the insured or the use of the drug to treat that psychiatric condition is otherwise supported by medical or scientific evidence;

b. The drug is prescribed by:
    i. A psychiatrist
    ii. A physician assistant under the supervision of a psychiatrist;
    iii. An advanced practice registered nurse who has the psychiatric training and experience prescribed by the State Board of Nursing pursuant to NRS 632.120; or
    iv. A primary care provider that is providing care to an insured in consultation with a practitioner listed in subparagraph (1), (2) or (3), if the closest practitioner listed in subparagraph (1), (2) or (3) who participates in the network plan of the insurer is located 60 miles or more from the residence of the insured; and

c. The practitioner listed in paragraph (b) who prescribed the drug knows, based on the medical history of the insured, or reasonably expects each alternative drug that is required to be used earlier in the step therapy protocol to be ineffective at treating the psychiatric condition…

3. As used in this section:
    c. *'Step therapy protocol' means a procedure that requires an insured to use a prescription drug or sequence of prescription drugs other than a drug that a practitioner recommends for treatment of a psychiatric condition of the insured before his or her policy of health insurance provides coverage for the recommended drug*."

Molina Reviewer Note: Medical necessity review for a psychiatric condition cannot require trial of other medications first. This is applicable to formulary medications that require prior authorization and non-formulary medications and is not limited to only medications designated 'ST'. If the requested drug is a brand name and the generic is on formulary, request can be reviewed for specific medical reason generic cannot be used.

BACKGROUND AND OTHER CONSIDERATIONS

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 to the 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 may not detect that the medication has been taken. If this occurs, the dosage should not be repeated.

Schizophrenia is a mental disorder that affects how a person thinks, feels and behaves. It affects about 1% of Americans and is characterized by delusions, hallucinations, and negative symptoms. Goals of therapy are to reduce symptoms and to improve quality of life. Bipolar I Disorder is a brain disorder characterized by manic episodes that last at least 7 days or are severe enough to require immediate hospital care. Depressive episodes usually follow the manic episodes. Current medications for bipolar

disorder include mood stabilizers, atypical antipsychotics, and antidepressants. The goal of treatment is to help patients gain better control of their mood swings. Depression is a serious mood disorder characterized by a consistent depressed mood or loss of interest in daily activities. This is a very common disorder that affects up to 6.9% of adults in the US. Antidepressants help improve the way the brain uses certain chemicals to regulate mood. Abilify MyCite is the first digital pill. In addition to sensing when a patient takes the pill, the app can also collect data on activity level and record self-reported data on rest and mood. The goal is to increase patient compliance with treatment regimen.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
The use of Abilify MyCite Kit (aripiprazole tablets with sensor) is not covered for all indications due to insufficient evidence to establish clinical effectiveness or superiority over standard aripiprazole or other atypical antipsychotics.

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.

Abilify MyCite (aripiprazole tablets with sensor) has a black box warning for increased mortality in elderly patients with dementia-related psychosis and suicidal thoughts and behaviors. 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. There is an increased risk of suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants. Closely monitor for worsening and emergence of suicidal thoughts and behaviors. The safety and effectiveness of Abilify MyCite have not been established in pediatric patients.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Abilify MyCite Starter Kit TBPK 2MG
Abilify MyCite Starter Kit TBPK 5MG
Abilify MyCite Starter Kit TBPK 10MG
Abilify MyCite Starter Kit TBPK 15MG
Abilify MyCite Starter Kit TBPK 20MG
Abilify MyCite Starter Kit TBPK 30MG
Abilify MyCite Maintenance Kit TBPK 2MG
Abilify MyCite Maintenance Kit TBPK 5MG
Abilify MyCite Maintenance Kit TBPK 10MG
Abilify MyCite Maintenance Kit TBPK 15MG
Abilify MyCite Maintenance Kit TBPK 20MG
Abilify MyCite Maintenance Kit TBPK 30MG
Abilify MyCite TABS 2MG
Abilify MyCite TABS 5MG
Abilify MyCite TABS 10MG
Abilify MyCite TABS 15MG
Abilify MyCite TABS 20MG
Abilify MyCite TABS 30MG

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Available Dosage Forms	Q1 2024
REVISION- Notable revisions: Required Medical Information Place of Administration FDA Approved Uses Background Contraindications/Exclusions/Discontinuation Other Special Considerations References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file