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Policy Number: C18385-A

Abilify MyCite Kit (aripiprazole tablets with sensor) MNR

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:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. FOR ALL INDICATIONS:
1. The member is using the requested drug for an FDA approved indication
   AND
2. (a) i. Documentation of treatment failure, serious side effects, or FDA labeled contraindication to

all preferred generic formulary oral atypical antipsychotic agents with matching indication
AND
ii. Documentation of treatment failure, serious side effects, or FDA labeled contraindication to all preferred long- acting injectable antipsychotics with matching indication

OR

(b) Documentation that the member is using the requested agent AND is at risk if therapy is changed OR has recently (within 48 hours) been discharged from the hospital on the requested agent

AND

3. Prescriber attestation that the member is able to swallow tablets whole and will not need to divide, crush, or chew tablets
   AND
4. Documentation the member is currently prescribed oral aripiprazole and is tolerating the medication
   AND
5. Member's adherence to aripiprazole is less than 80% of the time as confirmed by claims history within the last 3 months OR attestation from the Prescriber (review Rx history for compliance)
   AND
6. Documentation the member has tried ALL of the following adherence strategies: utilization of a pillbox, utilization of a smartphone reminder (alarm, application, or text reminder), involving family members or friends to assist, and coordinating timing of medication dose to coincide with dosing of another maintenance medication
   AND
7. Documentation the member has experienced life-threatening symptoms of their condition, or has experienced a severe worsening of the disease leading to a hospitalization due to lack of adherence to aripiprazole
   AND
8. Prescriber attests to all of the following:
   (a) The member is capable and has agreed to wear the Abilify MyCite weekly patch while on this medication
   (b) 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
   (c) The member has agreed to provide the prescriber or prescriber agent access to tracking and documenting the member's adherence through the 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 repeat life-threatening worsening of symptoms due to lack of adherence.

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% [DOCUMENTATION REQUIRED]
   AND
3. Prescriber attests to or clinical reviewer has found no evidence of 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
7. Prescriber 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

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

PRESCRIBER REQUIREMENTS:
None

AGE RESTRICTIONS:
18 years of age and older

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

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

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:
None

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.

Genetic Testing and Psychiatric Medication Choice

Pharmacogenomics is the study of the relationship between a genetic variation and how the body responds to medication. The America Psychiatric Association (APA) has a statement on pharmacogenomic testing based on results of their own task force looking at novel biomarkers and treatments. This task force determined "there is not sufficient information to support the widespread use of pharmacogenetic testing in clinical practice." The 2020 International Society of Psychiatric Genetics (ISPG) guidelines on genetic testing states "Pharmacogenetic testing should be viewed as a decision-support tool to assist in thoughtful implementation of good clinical care. We recommend HLA-A and HLA-B testing prior to use of carbamazepine and oxcarbazepine, in alignment with regulatory agencies and expert groups. Evidence to support widespread use of other pharmacogenetic tests at this time is still inconclusive, but when pharmacogenetic testing results are already available, providers are encouraged to integrate this information into their medication selection and dosing decisions. Genetic information for CYP2C19 and CYP2D6 would likely be most beneficial for individuals who have experienced an inadequate response or adverse reaction to a previous antidepressant or antipsychotic trial." The Pharmacogenomics

Knowledgebase (PharmGKB) has summaries of genotype-based *dosing* recommendations only, including the following:

- Aripiprazole: The Royal Dutch Pharmacists Association - Pharmacogenetics Working Group (DPWG) recommends reducing maximum dose of aripiprazole for patients carrying poor metabolizer alleles of CYP2D6.
- Antidepressants: The French National Network of Pharmacogenetics (Réseau national de pharmacogénétique (RNPGx)) recommends CYP2D6 and CYP2C19 genotyping before initiating an antidepressant treatment, especially in patients with a high risk of toxicity.
- Brexpiprazole: The Royal Dutch Pharmacists Association - Pharmacogenetics Working Group (DPWG) recommends to use half of the standard dose of brexpiprazole for patients carrying poor metabolizer alleles of CYP2D6.
- Duloxetine: There are currently no dosing recommendations for duloxetine based on CYP2D6 genotype.

At this time, there are no guidelines found that support the use of pharmacogenomic testing to make therapeutic treatment decisions based on the results of that testing. These tests may be beneficial to help guide dosing and toxicity concerns of specific agents for those with suboptimal responses or at risk of toxicity.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Abilify MyCite (aripiprazole tablets with sensor) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Abilify MyCite (aripiprazole tablets with sensor) include: known hypersensitivity to aripiprazole tablets.

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 References	Q1 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Drug Class Background Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file