Abilify Mycite
(aripiprazole tablets with sensor)

Policy Number: 5.01.697  Last Review: 05/2019
Origination: 05/2019  Next Review: 05/2020

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Abilify Mycite (aripiprazole tablets with sensor) when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Abilify Mycite (aripiprazole tablets with sensor) may be considered medically necessary when all of the following criteria are met:

Approve for 90 days for initial authorization.

1. Schizophrenia, Schizoaffective Disorder, or Bipolar I Disorder:
   a. The member must have one of the following clinically diagnosed conditions: Schizophrenia (acute/maintenance), Schizoaffective Disorder OR Bipolar I Disorder, AND
   b. The member must have documentation of prior therapy with aripiprazole AND prior therapy, intolerance, or contraindication to one of the following: risperidone or olanzapine or quetiapine or ziprasidone
   c. The member must have documentation of previous non-adherence that has led to failure to meet treatment goals

2. Major depressive disorder (bullet points below are all inclusive unless otherwise noted):
   a. The member must have clinically diagnosed major depressive disorder; AND
   b. The member must have prior therapy with aripiprazole AND prior therapy, intolerance, or contraindication to at least two antidepressant therapies (ADT); AND
   c. Abilify must be used as adjunctive or add-on treatment to ADT and not as monotherapy
   d. The member must have documentation of previous non-adherence that has led to failure to meet treatment goals
Reauthorization will be approved x 1 year if adherence has been improved/achieved with a corresponding benefit in meeting treatment goals.

**When Policy Topic is not covered**
Abilify Mycite (aripiprazole tablets with sensor) is considered **not medically necessary** when the above criteria is not met and **investigational** for all other uses, including:

1. **Dementia-related psychosis** (in the absence of an approvable diagnosis), for members 65 years of age or older.

**Considerations**
Abilify Mycite (aripiprazole tablets with sensor) requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, local medical policies of other health plans, Medicare (CMS), local providers.

**Description of Procedure or Service**
Abilify MyCite is a tablet formulation containing the atypical antipsychotic drug, aripiprazole, with an Ingestible Event Marker (IEM) sensor intended to track drug ingestion.

The mechanism of action of aripiprazole is different from those of the other atypical antipsychotics, as it acts as a D2 partial agonist. Aripiprazole is also a partial agonist at the 5-HT1A receptor, and like the other atypical antipsychotics displays an antagonist profile at the 5-HT2A receptor. It also antagonizes the 5-HT7 receptor and acts as a partial agonist at the 5-HT2C receptor, with latter pharmacologic action contributing to minimal weight gain. Aripiprazole has moderate affinity for histamine and α-adrenergic receptors and for the 5-HT transporter, and no appreciable affinity for cholinergic muscarinic receptors.

Abilify MyCite (aripiprazole tablets with sensor) is indicated for the treatment of adults with schizophrenia, acute treatment of adults with manic and mixed episodes associated with bipolar I disorder as monotherapy and as an adjunct to lithium or valproate, maintenance treatment of adults with bipolar I disorder as monotherapy and as an adjunct to lithium or valproate, and adjunctive treatment of adults with major depressive disorder.

Limitations of Use of Abilify MyCite (aripiprazole tablets with sensor): The ability to improve patient compliance or modify aripiprazole dosage has not been established and tracking drug ingestion in “real-time” or during an emergency is not recommended because detection may be delayed or not occur.
Aripiprazole for oral administration is available as Abilify and Abilify MyCite in 2mg, 5mg, 10mg, 15mg, 20mg, and 30mg tablets, a 1mg/mL solution, and as Abilify Discmelt in 10mg and 15mg fast-dissolving tablets.

**Rationale**

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Abilify Mycite (aripiprazole tablets with sensor) while maintaining optimal therapeutic outcomes.

References

**Billing Coding/Physician Documentation Information**

| N/A | Pharmacy benefit |

**Additional Policy Key Words**

N/A
Policy Implementation/Update Information

05/2019 | New policy titled Abilify Mycite (aripiprazole tablets with sensor)

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.