Abilify Mycite

Description

Abilify Mycite (aripiprazole tablets with sensor)

Background

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. Aripiprazole’s mechanism of action is thought to be due to a combination of partial agonist activity at D2 and 5-HT1A receptors and antagonist activity at 5-HT2A receptors (1).

The Abilify Mycite System is composed of the following components:

- Aripiprazole tablet embedded with IEM sensor (Abilify Mycite);
- Mycite Patch (wearable sensor) that detects the signal from the IEM sensor after ingestion and transmits data to a smartphone;
- Mycite App – a smartphone application which is used with a compatible smartphone to display information for the patient;
- Web-based portal for healthcare professionals and caregivers.

Regulatory Status

FDA-approved indication: Abilify Mycite is indicated for the: (1)

- 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
Abilify Mycite may be considered **medically necessary** for patients 18 years of age and older for the treatment of schizophrenia, bipolar disorder, or depression and if the conditions indicated below are met.
Abilify Mycite is considered *investigational* in patients less than 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age** 18 years of age or older

**Diagnoses**

Patient must have **ONE** of the following:

1. Schizophrenia  
2. Bipolar I disorder  
3. Major depressive disorder (MDD) as adjunctive treatment

**AND ALL** of the following:

a. Inadequate treatment response to Abilify (aripiprazole) due to non-compliance  
b. Inadequate treatment response, intolerance, or contraindication to a long-acting injectable antipsychotic  
c. Monthly monitoring via the portal by the prescriber and/or designated person(s)  
d. Prescriber agrees to monitor for neuroleptic malignant syndrome and for increased risk of suicidal thoughts and behaviors  
e. **NO** dementia-related psychosis

**Prior – Approval Renewal Requirements**

**Age** 18 years of age or older

**Diagnoses**

Patient must have **ONE** of the following:

1. Schizophrenia  
2. Bipolar I disorder  
3. Major depressive disorder (MDD) as adjunctive treatment
AND ALL of the following:
  a. Monthly monitoring via the portal by the prescriber and/or designated person(s)
  b. Prescriber agrees to monitor for neuroleptic malignant syndrome and for increased risk of suicidal thoughts and behaviors
  c. NO dementia related psychosis

**Policy Guidelines**

**Pre - PA Allowance**
None

**Prior - Approval Limits**

<table>
<thead>
<tr>
<th>Quantity</th>
<th>90 tablets per 90 days</th>
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<tr>
<td>Duration</td>
<td>12 months</td>
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**Prior – Approval Renewal Limits**
Same as above

**Rationale**

**Summary**
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. Aripiprazole’s mechanism of action is thought to be due to a combination of partial agonist activity at D2 and 5-HT1A receptors and antagonist activity at 5-HT2A receptors. Safety and effectiveness of Abilify Mycite in pediatric patients less than 18 years of age have not been established. Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric patients less than 18 years of age have not been established.

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Abilify Mycite while maintaining optimal therapeutic outcomes.

**References**
Section: Prescription Drugs  Effective Date: January 1, 2020
Subsection: Central Nervous System Drugs  Original Policy Date: October 11, 2019
Subject: Abilify Mycite  Page: 5 of 5

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>October 2019</td>
<td>Addition to PA</td>
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<tr>
<td>December 2019</td>
<td>Annual review</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.