BlueCross BlueShield
Federal Employee Program

ABILIFY MYCITE
(aripiprazole tablets with sensor)

RATIONALE FOR INCLUSION IN PA PROGRAM

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 unknown. However, the efficacy of aripiprazole could be mediated through a combination of partial agonist activity at D_2 and 5-HT_{1A} receptors and antagonist activity at 5-HT_{2A} 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 indications: 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
    - 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 the 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 (1).

Abilify Mycite carries a boxed warning on the risk of increased mortality in elderly patients with

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dementia-related psychosis. 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 (1).

Abilify Mycite also carries a boxed warning on the increased risk of suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants. Patients should be monitored closely for worsening and emergence of suicidal thoughts and behaviors (1).

Abilify Mycite should be discontinued in case of severe neutropenia (absolute neutrophil count <1000/mm^3), tardive dyskinesia if clinically appropriate, and neuroleptic malignant syndrome (1).

Abilify Mycite should be used with caution in patients with a history of seizures or with conditions that potentially lower the seizure threshold (1).

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 (1).

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 D_2 and 5-HT_{1A} receptors and antagonist activity at 5-HT_{2A} 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 (1).

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

References

1. Abilify Mycite [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; February 2023.