BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.60.040

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	October 11, 2019
Subject:	Abilify Mycite	**Page:**	1 of 5

Last Review Date: December 13, 2024

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 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 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).

Related policies

Lybalvi, Zyprexa Relprevv

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Abilify Mycite may be considered **medically necessary** if the conditions indicated below are met.

Abilify Mycite may be considered **investigational** 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

Quantity 90 tablets per 90 days

Duration 12 months

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 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.

Policy History

Date	Action

October 2019	Addition to PA
December 2019	Annual review
December 2020	Annual review and reference update
March 2021	Annual editorial review and reference update
December 2021	Annual review
March 2022	Annual review
March 2023	Annual review and reference update. Changed policy number to 5.60.040
September 2023	Annual review
December 2023	Annual review
March 2024	Annual review and reference update
December 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.