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Abilify Mycite

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy addresses the usage of aripiprazole tablets with an Ingestible Event Marker (IEM) sensor (Abilify Mycite®).

Note: *Abilify Mycite is FDA-approved for the treatment of adults with schizophrenia, treatment of bipolar I disorder and adjunctive treatment of adults with major depressive disorder (MDD).*

Conditions Not Covered

The effectiveness of Abilify Mycite (aripiprazole tablets with an Ingestible Event Marker [IEM] sensor) has not been demonstrated as clinically superior to generic aripiprazole tablets for the treatment of adults with schizophrenia, bipolar I disorder or adjunctive treatment of adults with major depressive disorder (MDD), and is significantly more expensive. Coverage of Abilify Mycite may depend on the applicable health benefit plan definition of medical necessity. Where that definition limits coverage to the most cost-effective equivalent treatment, Abilify Mycite is not considered medically necessary.

Background

OVERVIEW
Abilify Mycite, a drug-device combination product comprised of aripiprazole tablets embedded with an Ingestible Event Marker (IEM) sensor intended to track drug ingestion, 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 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.

References

1. Abilify Mycite® tablets with sensor [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical, Inc; April 2021.