Abilify MyCite® (aripiprazole tablets with sensor) – New drug approval

- On November 13, 2017, the FDA announced the approval of Otsuka and Proteus' Abilify MyCite (aripiprazole tablets with sensor), a drug-device combination product comprised of oral aripiprazole tablets embedded with an ingestible event marker (IEM) sensor.
    - Abilify MyCite is the first digital ingestion tracking system approved in the U.S.
- Abilify MyCite is approved for the following conditions:
    - Treatment of adults with schizophrenia
    - Acute treatment of bipolar I disorder in adults with manic and mixed as monotherapy and as adjunct to lithium or valproate
    - Maintenance treatment of bipolar I disorder in adults as monotherapy and as adjunct to lithium or valproate
    - Adjunctive treatment of adults with major depressive disorder
- Abilify MyCite is intended to track if the medication has been taken. The Abilify MyCite system includes aripiprazole tablets embedded with an IEM sensor, a MyCite patch (wearable sensor), MyCite smartphone application to display information for the patient, and a web-based portal for healthcare providers and caregivers.
    - The IEM sensor is the size of a grain of sand and is made up of ingredients found in food. The IEM sensor activates when in contact with stomach fluid and communicates to the MyCite patch. The IEM sensor is then digested and eliminated from the body.
    - The MyCite patch detects and records the date and time of the tablet ingestion and certain physiological data, such as activity level, and communicates this to the MyCite smartphone application.
    - Web-based dashboards are provided to healthcare providers and caregivers. With patient consent, select members of the family and care team may also access information.
- The approval of Abilify MyCite was based, in part, on the clinical trial data and experience of oral Abilify. However, the ability of Abilify MyCite to improve patient compliance or modify aripiprazole dosage has not been established.
- Similar to Abilify, Abilify MyCite carries a boxed warning regarding increased mortality in elderly patients with dementia-related psychosis and suicidal thoughts and behaviors.
- The warnings and precautions, adverse reactions, and dosage of Abilify MyCite are similar to oral Abilify. Refer to the Abilify MyCite drug label for additional details.
    - Skin irritation at the site of the MyCite patch placement may occur in some patients.
    - It can take 30 minutes to 2 hours to detect ingestion of the tablet. Sometimes the system may not detect that the medication has been taken. If this occurs, the dosage should not be repeated.
    - 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.

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- Otsuka and Proteus plan to launch Abilify MyCite in phases to obtain, and respond to, feedback from healthcare providers and their patients. Abilify MyCite will be available as a kit containing aripiprazole tablets embedded with an IEM sensor co-packaged with 7 MyCite patches. Aripiprazole tablets with sensor will be available as 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg.