DRUG REVIEW:

ABILIFY MYCITE

Review Date: 04/18/18

Generic: aripiprazole tablets with sensor (FDA approved 11/13/2017, Abilify approved in 2002, sensor approved in 2012)

Company: Otsuka Pharmaceutical Co., Ltd., Proteus Digital Health

Agent for: Schizophrenia, bipolar I disorder, and depression

Indications: Treatment of adults with schizophrenia, acute treatment of manic and mixed episodes for adults with bipolar I disorder and maintenance treatment for bipolar I disorder, and adjunctive treatment for adults with major depressive disorder

Mechanism of Action: Mechanism of aripiprazole is unknown but activity with D_2, 5-HT_{1A}, and 5-HT_{2A} receptors are believed to contribute. Tablets are embedded with an Ingestible Event Marker sensor which is detected by a wearable patch when activated by stomach acid to transmit data to a smartphone that can be accessed via an app. Providers can also access this information via a web based dashboard.

COMPARABLE DRUG: Aripiprazole(Abilify), risperidone (Risperdal), quetiapine (Seroquel), olanzapine (Zyprexa), paliperidone (Invega), asenapine (Saphris), cariprazine (Vraylar), clozapine (Clozaril)

COST PER MONTH (WAC)

ABILIFY MYCITE: N/A
ABILIFY (15 MG): $891.97
RISPERDAL (4 MG): $1,694.34
SEROQUEL (200MG): $1,257.75
ZYPREXA (20 MG): $1,216.20
INVEGA (9 MG): $1,661.52
SAPHRIS (10 MG): $1,200.81
VRAYLAR (6 MG): $1,200.81
CLOZARIL (100 MG): $1,396.29

ADVANTAGES:

- Ability to track ingestion of medications may be useful for patients
- Provides a resource for providers to assess adherence to treatment

DISADVANTAGES:

- Ability of product to improve patient compliance with treatment regime has not been shown
- Use in "real time" or during an emergency is not recommended because detection may be delayed or not occur

MOST IMPORTANT RISKS/ADVERSE EVENTS: For the elderly with dementia-related psychosis, an increased risk of death may occur. Patients taking antidepressants may also have an increased risk of suicidal thinking and behavior.

MOST COMMON ADVERSE EVENTS: Common side effects include nausea, vomiting, constipation, headache, dizziness, akathisia, anxiety, insomnia, sedation, fatigue and restlessness.

USUAL DOSAGE: Dosage varies based on indication. Recommended dose for adults with schizophrenia is 10-15 mg daily. Maximum dosage is 30 mg but doses above 15 mg have not been shown to have additional clinically meaningful benefits. Recommended starting dose for Bipolar I Disorder is 15 mg as monotherapy and 10-15 mg as adjunctive therapy. Recommended starting dose for depression is 2-5 mg daily and the recommended dosage range is 2-15 mg daily. The patch should be applied when instructed by the app to the left side of the body above the lower edge of the rib cage. The patch should be changed weekly.

PRODUCT: Abilify MyCite is a drug-device combination product. It is administered orally and should not be divided, crushed or chewed. The color and shape of the tablet varies based on strength. The strengths are 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg.

COMMENTS: Schizophrenia is a mental disorder that affects how a person thinks, feels and behaves. It affects about 1% of Americans and is characterized by delusions, hallucinations and negative symptoms. Goals of therapy are to reduce symptoms and to improve quality of life. Bipolar I Disorder is a brain disorder characterized by manic episodes that last at least 7 days or are severe enough to require immediate hospital care.

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Depressive episodes usually follow the manic episodes. Current medications for bipolar disorder include mood stabilizers, atypical antipsychotics and antidepressants. The goal of treatment is to help patients gain better control of their mood swings. Depression is a serious mood disorder characterized by a consistent depressed mood or loss of interest in daily activities. This is a very common disorder that affects up to 6.9% of adults in the US. Antidepressants help improve the way the brain uses certain chemicals to regulate mood. Abilify MyCite is the first digital pill. In addition to sensing when a patient takes the pill, the app can also collect data on activity level and record self-reported data on rest and mood. The goal is to increase patient compliance with treatment regime. The product will be available as a slow launch in 2018.