

## **ABILIFY® (aripiprazole) Testimony – Montana Medicaid**

My name is Samantha Min, and I am a Managed Market Liaison with Otsuka America Pharmaceutical, Inc. Thank you for this opportunity to provide information on ABILIFY to Montana Medicaid P&T members. I believe you all have received and/or reviewed the full PI information, so I would like to highlight the following new indication:

### **ABILIFY**

#### **INDICATIONS AND USAGE<sup>1</sup>**

ABILIFY is approved for a broad range of indications, in both the adult and pediatric populations, and is available in multiple dosage forms, including tablets, orally disintegrating tablets, oral solution, and acute intramuscular injection. The safety and efficacy of aripiprazole has been studied in multiple psychiatric diagnoses, resulting in 15 FDA- approved indications.

- Treatment of Tourette's disorder in pediatric patients (6-18 years)
- Treatment of schizophrenia in adults and adolescents age 13-17
- Acute treatment of manic or mixed episodes associated with bipolar I disorder as monotherapy and as an adjunct to lithium or valproate in adult and pediatric patients age 10 to 17
- Maintenance treatment of bipolar I disorder, both as monotherapy and as an adjunct to lithium or valproate in adult and pediatric patients age 10 to 17
- Use as an adjunctive therapy to antidepressants for major depressive disorder (MDD) in adults.
- Treatment of irritability associated with autistic disorder in pediatric patients age 6-17
- Aripiprazole intramuscular (IM) formulation is indicated for acute treatment of agitation associated with schizophrenia or bipolar mania in adults

#### **SAFETY<sup>1</sup>**

*I call your attention to the two Boxed Warnings for ABILIFY (1) Increased Mortality in Elderly Patients with Dementia-Related Psychosis and (2) Suicidal Thoughts and Behaviors with Antidepressant Drugs in children, adolescents, and young adults. For the complete boxed warning and additional information, I have available for you today the full Prescribing Information for ABILIFY.*

#### **TOURETTE'S DISORDER IN PEDIATRIC PATIENTS<sup>1</sup>**

The efficacy of ABILIFY (aripiprazole) in the treatment of Tourette's disorder was established in one 8-week (7 to 17 years of age) and one 10-week (6 to 18 years of age), placebo-controlled trials who met the DSM-IV criteria for Tourette's disorder and had a Total Tic score (TTS)  $\geq 20$  - 22 on the Yale Global Tic Severity Scale (YGTSS). The YGTSS is a fully validated scale designed to measure current tic severity. Efficacy was evaluated using two assessment scales: 1) the TTS of the YGTSS and 2) the Clinical Global Impressions Scale for Tourette's Syndrome (CGI-TS), a clinician-determined summary measure that takes into account all available patient information. Over 65% of these patients were under 13 years of age.

The primary outcome measure in both trials was the change from baseline to endpoint in the TTS of the YGTSS. Ratings for the TTS are made along 5 different dimensions on a scale of 0 to 5 for motor and vocal tics each. Summation of these 10 scores provides a TTS (i.e., 0-50).

The results of these trials are as follows: In the 8-week, placebo-controlled, fixed-dose trial, 133 children and adolescents with Tourette's disorder, aged 7 to 17 years, were randomized 1:1:1 to low dose ABILIFY, high dose ABILIFY, or placebo. The target doses for the low and high dose ABILIFY groups were based on weight (<50 kg or  $\geq 50$  kg). Patients in all ABILIFY groups started at 2 mg per day and were titrated to the target dose (5, 10, or 20 mg/day). ABILIFY (both high and low dose groups) demonstrated statistically significantly improved scores on the YGTSS TTS and on the CGI-TS scale compared with placebo. In the 10-week, placebo-controlled, flexible-dose trial, 61 children and adolescents with Tourette's disorder, aged 6 to 18 years, received daily doses of placebo or ABILIFY, starting at 2 mg/day with increases allowed up to 20 mg/day based on clinical response. ABILIFY demonstrated statistically significantly improved scores on the YGTSS TTS scale compared with placebo.

Commonly observed adverse reactions associated with the use of ABILIFY in pediatric patients with Tourette's disorder (incidence of 5% or greater and ABILIFY incidence at least twice that for placebo) were sedation, somnolence, nausea, headache, nasopharyngitis, fatigue, and increased appetite.

PLEASE REFER TO THE ATTACHED ABILIFY PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION.

**SUMMARY**

In closing, Otsuka America Pharmaceutical, Inc. respectfully asks that ABILIFY remain on formulary in the state of Montana. Upon request, I am happy to provide the committee with any specific medical information you need.

**REFERENCES**

1. ABILIFY® (aripiprazole) FULL PRESCRIBING INFORMATION. Otsuka America Pharmaceutical, Inc.