**INDICATION**

ABILIFY MAINTENA® (aripiprazole) is an atypical antipsychotic indicated for the treatment of schizophrenia.

**WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS**

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk (1.6 to 1.7 times) of death compared to placebo (4.5% vs 2.6%, respectively). Although the causes of death were varied, most of the deaths appeared to be cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Aripiprazole is not approved for the treatment of patients with dementia-related psychosis.

**Important Warning and Precaution Regarding Potential for Cognitive and Motor Impairment:**

Aripiprazole may impair judgment, thinking, or motor skills. Instruct patients to avoid operating hazardous machinery, including automobiles, until they are certain aripiprazole does not affect them adversely.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
Schizophrenia treatment goals

GOALS ACROSS 3 PHASES INCLUDE²:

**ACUTE PHASE**
- Reduce the severity of the acute psychotic episode
- Address factors that led to the acute episode
- Develop an alliance with the patient and family
- Formulate short- and long-term treatment plans
- Connect the patient with appropriate aftercare in the community

**STABILIZATION PHASE**
- Provide support to delay the likelihood of relapse
- Plan for the patient’s adaptation to life in the community
- Maintain reduction in symptoms
- Promote follow-up appointment with outpatient psychiatrist

**STABLE PHASE**
- Sustain symptom control
- Monitor patient for relapse
- Monitor continually for adverse treatment effects
- Consider psychosocial interventions

Adapted from American Psychiatric Association guidelines.

- It is important to minimize gaps in service delivery, because patients are vulnerable to relapse and need support adjusting to community life²
- Many patients with schizophrenia do not receive timely outpatient treatment following discharge³
  — In a retrospective review of 59,567 Medicaid hospital discharges, only 41.7% had schizophrenia-related outpatient visits by 7 days following discharge, and 59.3% by 30 days

**Contraindication:**
Known hypersensitivity reaction to aripiprazole. Reactions have ranged from pruritis/urticaria to anaphylaxis.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
HEDIS 2017 CRITERIA RELATED TO ASSESSMENT OF PATIENTS⁴

- The NCQA developed a tool called HEDIS that measures the performance of healthcare plans, and is used by more than 90% of health plans in the United States.

HEDIS QUALITY OF CARE METRICS FOR PATIENTS WITH SCHIZOPHRENIA INCLUDE⁵:

- Follow-up After Hospitalization for Mental Illness*
- Follow-up After Emergency Department Visit for Mental Illness†
- Diabetes Screening for People With Schizophrenia Who Are Using Antipsychotic Medications‡
- Diabetes Monitoring for People With Diabetes and Schizophrenia‡
- Cardiovascular Monitoring for People With Cardiovascular Disease and Schizophrenia‡
- Annual Monitoring for Patients on Persistent Medications*
- Medication Reconciliation Post-Discharge§

*For use by commercial health plans, Medicaid, and Medicare.
†First-year measure.
‡For use by Medicaid only.
§For use by Medicare only.

HEDIS=Healthcare Effectiveness Data and Information Set; NCQA=National Committee for Quality Assurance.

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Important Warning and Precaution Regarding Cerebrovascular Adverse Events, Including Stroke:

Increased incidence of cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, have been reported in clinical trials of elderly patients with dementia-related psychosis treated with oral aripiprazole.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
In the treatment of schizophrenia

Considerations for LAI utilization

**POTENTIAL ADVANTAGES INCLUDE:**
- Identification of patients who miss doses\(^5\text{–}12\)
- Ability to distinguish a relapse due to inadequate response to pharmacotherapy from relapse due to other factors\(^7\text{,}9\)
- Avoidance of first-pass metabolism\(^6\text{,}10\text{,}12\)
- Lower potential for medication to be taken incorrectly\(^7\text{,}10\)
- Some may find less frequent dosing more practical\(^8\text{,}9\)

**POTENTIAL DISADVANTAGES INCLUDE:**
- Requires slow dose titration and longer time to achieve steady-state plasma concentrations\(^7\)
- Oral supplements may add to complexity of titration process\(^7\)
- Discomfort at injection site\(^6\text{,}7\text{,}10\text{,}12\)
- Side effects may persist beyond treatment termination\(^6\text{,}7\text{,}10\)
- Patient resistance to injections\(^6\text{,}10\)

Not all LAIs may carry these potential advantages/disadvantages.

LAI=long-acting injectable.

**Important Warning and Precaution Regarding Metabolic Changes:**
Atypical antipsychotic drugs have been associated with metabolic changes that include:
- **Hyperglycemia/Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis, or hyperosmolar coma, or death, has been reported in patients treated with atypical antipsychotics including aripiprazole. Assess fasting plasma glucose before or soon after initiation of antipsychotic medication, and monitor periodically during long-term treatment.
- **Dyslipidemia:** Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.
- **Weight Gain:** Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
Choosing appropriate care for the acutely relapsed patient

HISTORY

• Hospitalized 4 times over the past 6 years, most recently 1 year ago
• Switched to a different oral antipsychotic with each hospitalization

CURRENT EPISODE

• The group-home staff observed that Anthony is looking more disheveled and spending most of the day alone in his room
• Over the past 2 days, he appears to be responding to internal stimuli and accusing his roommate of stealing from him
• This morning Anthony became agitated and began to shout at the staff when they reminded him about the importance of taking his medication
• After an ACT team assessment, Anthony was admitted to the hospital due to command hallucinations to harm himself
• Anthony seems to have little insight into the importance of taking his schizophrenia medication every day

WHAT ARE YOUR TREATMENT GOALS FOR A PATIENT LIKE ANTHONY?

Diagnosed with schizophrenia 6 years ago
Lives in a group home
Currently receives Medicaid benefits

ACT=Assertive Community Treatment.

Important Warning and Precaution Regarding Neuroleptic Malignant Syndrome (NMS):
A potentially fatal symptom complex sometimes referred to as NMS may occur with administration of antipsychotic drugs, including aripiprazole. Rare cases of NMS occurred during aripiprazole treatment. Signs and symptoms of NMS include hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (e.g., irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
A randomized, double-blind, placebo-controlled clinical study of 340 acutely relapsed adult patients with schizophrenia to determine the efficacy and safety of ABILIFY MAINTENA® (aripiprazole) 400 mg (n=168) vs placebo (n=172). All patients had a diagnosis of schizophrenia for ≥1 year at study entry. Patients were required to remain as inpatients for at least the first 2 weeks of treatment, and those discharged were followed with clinic visits and phone calls.

**DISCONTINUATIONS**

<table>
<thead>
<tr>
<th>ABILIFY MAINTENA</th>
<th>PLACEBO</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=60 Discontinued prior to Week 10</td>
<td>n=87 Discontinued prior to Week 10</td>
</tr>
</tbody>
</table>

- 32 Patient withdrew consent
- 12 Lack of efficacy
- 7 Adverse events (AE)
- 6 Other
- 3 Lost to follow-up

- 15 Patient withdrew consent
- 50 Lack of efficacy
- 13 Adverse events
- 5 Other
- 4 Lost to follow-up

*Baseline characteristics: PANSS Total Score ≥80 and a PANSS score >4 on each of 4 specific psychotic symptoms (conceptual disorganization, hallucinatory behavior, suspiciousness/persecution, and unusual thought content) at screening and baseline; diagnosis of schizophrenia ≥1 year.*

See clinical study information on pages 7, 8, 12, and 13.

**Important Warning and Precaution Regarding Tardive Dyskinesia (TD):**
The risk of developing TD (a syndrome of abnormal, involuntary movements) and the potential for it to become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic increase. The syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. Prescribing should be consistent with the need to minimize TD. There is no known treatment for established TD, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
Antipsychotic medications prior to study enrollment\textsuperscript{1,14}\textsuperscript{†}

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Patients Receiving</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral aripiprazole</td>
<td>6.5%</td>
</tr>
<tr>
<td>Total receiving other/no antipsychotic</td>
<td>93.5%</td>
</tr>
<tr>
<td>No antipsychotic</td>
<td>26.5%</td>
</tr>
<tr>
<td>Other</td>
<td>22%</td>
</tr>
<tr>
<td>Risperidone</td>
<td>21.5%</td>
</tr>
<tr>
<td>Quetiapine</td>
<td>15.3%</td>
</tr>
<tr>
<td>Olanzapine</td>
<td>8.2%</td>
</tr>
</tbody>
</table>

All patients underwent a 7-day washout period at study entry.

\textsuperscript{†}For patients naïve to aripiprazole, establish tolerability with oral aripiprazole prior to initiating ABILIFY MAINTENA. Due to the half-life of oral aripiprazole, it may take up to 2 weeks to fully assess tolerability.

Important Warning and Precaution Regarding Pathological Gambling and Other Compulsive Behaviors:

Intense urges, particularly for gambling, and the inability to control these urges have been reported while taking aripiprazole. Other compulsive urges (e.g., eating, sexual, or shopping) have been reported less frequently. Prescribers should ask patients or their caregivers specifically about, and closely monitor for, the development of new or intense compulsive urges. Consider dose reduction or stopping aripiprazole, if such urges develop.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
Early and continued symptom improvement in markedly ill* patients—CGI-S score¹

**KEY SECONDARY EFFICACY ENDPOINT**
Mean change in CGI-S score from baseline to Week 10²

*P<0.001; bP<0.0001; 
(95% CI, -1.1, -0.6).
CGI-S=Clinical Global Impression-Severity.

**Important Warning and Precaution Regarding Orthostatic Hypotension:**
Aripiprazole may cause orthostatic hypotension and should be used with caution in patients with known cardiovascular disease, cerebrovascular disease, or conditions which would predispose them to hypotension.

Please see study design on page 6.

**Mean CGI-S scores at efficacy endpoint¹⁵,¹⁶**

<table>
<thead>
<tr>
<th>Illness Level</th>
<th>Mean CGI-S Score (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Among the most</td>
<td>-0.6 (SD 0.8)</td>
</tr>
<tr>
<td>extremely ill patients</td>
<td></td>
</tr>
<tr>
<td>Severely ill</td>
<td>-4.4 (SD 1.0)</td>
</tr>
<tr>
<td>Markedly ill</td>
<td></td>
</tr>
<tr>
<td>Moderately ill</td>
<td></td>
</tr>
<tr>
<td>Mildly ill</td>
<td>-3.6 (SD 0.8)</td>
</tr>
<tr>
<td>Borderline mentally ill</td>
<td></td>
</tr>
<tr>
<td>Not at all ill</td>
<td></td>
</tr>
</tbody>
</table>

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
Study design in maintenance treatment

For patients with schizophrenia

52-WEEK STUDY

A multiphase study of ABILIFY MAINTENA® (aripiprazole) vs placebo in which patients with a diagnosis of schizophrenia ≥3 years were stabilized on oral aripiprazole 10 mg to 30 mg/day during the open-label second phase. Then patients were converted to and stabilized on ABILIFY MAINTENA 400 mg in the single-blind third phase, during which they also continued on oral aripiprazole 10 mg to 20 mg for the first 14 days following the initial ABILIFY MAINTENA dose. During the double-blind, placebo-controlled fourth phase, patients were randomized to either IM ABILIFY MAINTENA (n=269) or IM placebo (n=134).

REASON FOR DISCONTINUATIONS BY PHASE

<table>
<thead>
<tr>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Phase 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>(n=633)</td>
<td>(n=710)</td>
<td>(n=576)</td>
<td>ABILIFY MAINTENA (n=269) Placebo (n=134)</td>
</tr>
<tr>
<td>n=133 Discontinued</td>
<td>n=134 Discontinued</td>
<td>n=173 Discontinued</td>
<td>n=246 Discontinued</td>
</tr>
<tr>
<td>54 Sponsor discontinued trial</td>
<td>42 Sponsor discontinued trial</td>
<td>86 Sponsor discontinued trial</td>
<td>179 Sponsor discontinued trial due to positive interim analysis</td>
</tr>
<tr>
<td>13 Lost to follow-up</td>
<td>7 Lost to follow-up</td>
<td>11 Lost to follow-up</td>
<td>9 Adverse events</td>
</tr>
<tr>
<td>24 Withdrew consent</td>
<td>29 Withdrew consent</td>
<td>29 Withdrew consent</td>
<td>11 Relapse (with AE)</td>
</tr>
<tr>
<td>11 Adverse events (AE)</td>
<td>14 Adverse events (AE)</td>
<td>17 Adverse events (AE)</td>
<td>16 Relapse (without AE)</td>
</tr>
<tr>
<td>21 Lack of efficacy (with or without AE)</td>
<td>11 Lack of efficacy (with or without AE)</td>
<td>13 Lack of efficacy (with or without AE)</td>
<td>14 Withdrew consent</td>
</tr>
<tr>
<td>10 Other</td>
<td>31 Other</td>
<td>17 Other</td>
<td>17 Other</td>
</tr>
<tr>
<td>58 Sponsor discontinued trial due to positive interim analysis</td>
<td>58 Sponsor discontinued trial due to positive interim analysis</td>
<td>58 Sponsor discontinued trial due to positive interim analysis</td>
<td>58 Sponsor discontinued trial due to positive interim analysis</td>
</tr>
<tr>
<td>13 Relapse (without AE)</td>
<td>13 Relapse (without AE)</td>
<td>13 Relapse (without AE)</td>
<td>13 Relapse (without AE)</td>
</tr>
<tr>
<td>4 Other</td>
<td>4 Other</td>
<td>4 Other</td>
<td>4 Other</td>
</tr>
</tbody>
</table>

See clinical study information on pages 10 and 11.

IM=intramuscular.

Important Warning and Precaution Regarding Falls:

Antipsychotics may cause somnolence, postural hypotension, motor and sensory instability, which may lead to falls causing fractures or other injuries. For patients with diseases, conditions, or medications that could exacerbate these effects, complete fall risk assessments when initiating treatment and recurrently during therapy.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
Only 10% of patients on ABILIFY MAINTENA relapsed* vs 40% on placebo (P<0.0001)\textsuperscript{17,18†}

**KEY SECONDARY ENDPOINT**

Percent of patients meeting relapse criteria

*Relapse was defined as clinical worsening, psychiatric hospitalization, increased risk of suicide, or violent behavior.
†At the final analysis time point (80 events).
‡Percent of patients who did not meet relapse criteria.

90% of patients were relapse-free\textsuperscript{†} vs 60% on placebo at study end\textsuperscript{17,18}

**PRIMARY ENDPOINT**

Time from randomization to relapse—ABILIFY MAINTENA significantly delayed time to relapse* vs placebo (P<0.0001)\textsuperscript{17†}

Please see study design on page 9.

**Important Warning and Precaution Regarding Leukopenia, Neutropenia, and Agranulocytosis:**

Leukopenia, neutropenia, and agranulocytosis have been reported. In patients with a history of clinically significant low white blood cell count (WBC)/absolute neutrophil count (ANC) or history of drug-induced leukopenia/neutropenia, perform a complete blood count (CBC) frequently during the first few months of therapy. Consider discontinuing aripiprazole at the first sign of a clinically significant decline in WBC in the absence of other causative factors. Monitor patients with clinically significant neutropenia for fever or other symptoms or signs of infection and treat promptly if such symptoms or signs occur. Discontinue aripiprazole in patients with severe neutropenia (ANC <1000/mm\textsuperscript{3}) and follow their WBC counts until recovery.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
Symptom control maintained in a 52-week study

Distribution of Oral Aripiprazole Dosage at the End of Phase 2—Prior to First ABILIFY MAINTENA Injection

<table>
<thead>
<tr>
<th>Dosage</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mg</td>
<td>75</td>
<td>13.0%</td>
</tr>
<tr>
<td>15 mg</td>
<td>192</td>
<td>33.3%</td>
</tr>
<tr>
<td>20 mg</td>
<td>114</td>
<td>19.8%</td>
</tr>
<tr>
<td>25 mg</td>
<td>48</td>
<td>8.3%</td>
</tr>
<tr>
<td>30 mg</td>
<td>147</td>
<td>25.5%</td>
</tr>
</tbody>
</table>

- Patients were stabilized on oral aripiprazole (10 to 30 mg/day) in the oral stabilization phase

Maintained symptom control vs placebo in Phase 4

- Significant difference in PANSS Total Score vs placebo starting at Week 2 in double-blind Phase 4 and at all subsequent time points
  - All comparisons vs placebo are adjusted mean changes from baseline in Phase 4 (Week 2: P<0.05; Week 4: P<0.001; Weeks 6 through 52: P<0.0001)

Important Warning and Precaution Regarding Seizures:
Aripiprazole should be used with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
ABILIFY MAINTENA HAS BEEN EVALUATED FOR SAFETY IN 2188 ADULT PATIENTS

The following safety information is derived from a 12-week, double-blind study or an open-label study.

- Most commonly observed adverse reactions (incidence ≥5% for ABILIFY MAINTENA and at least twice that for placebo) were increased weight (16.8% vs 7.0%), akathisia (11.4% vs 3.5%), injection site pain (5.4% vs 0.6%), and sedation (5.4% vs 1.2%)

  - The mean intensity of injection pain reported by patients using a visual analog scale (0=no pain to 100=unbearably painful) approximately 1 hour after injection was 7.1 (SD 14.5) for the first injection and 4.8 (SD 12.4) at the last visit

- The incidence of discontinuation before Week 10 due to adverse reactions was 4.2% for patients on ABILIFY MAINTENA and 7.6% for placebo

- In an open-label study comparing bioavailability of ABILIFY MAINTENA administered in the deltoid or gluteal muscle, injection site pain was observed in both groups at approximately equal rates

(continued on next page)

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.

Adverse reactions in ≥2% of ABILIFY MAINTENA–treated adult patients with schizophrenia in a 12-week, double-blind, placebo-controlled study

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Preferred Term</th>
<th>Percentage of Patients Reporting Reaction*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ABILIFY MAINTENA (n=167)</td>
<td>Placebo (n=172)</td>
</tr>
<tr>
<td>Gastrointestinal Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constipation</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Dry Mouth</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Vomiting</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Abdominal Discomfort</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>General Disorders and Administration Site Conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection Site Pain</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Infections and Infestations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper Respiratory Tract Infection</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Investigations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased Weight</td>
<td>17</td>
<td>7</td>
</tr>
<tr>
<td>Decreased Weight</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Musculoskeletal and Connective Tissue Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arthralgia</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Back Pain</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Myalgia</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Musculoskeletal Pain</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Nervous System Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Akathisia</td>
<td>11</td>
<td>4</td>
</tr>
<tr>
<td>Sedation</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Dizziness</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Tremor</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Respiratory, Thoracic, and Mediastinal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nasal Congestion</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

*Table excludes adverse reactions that had an incidence equal to or less than placebo.
The following safety information is derived from a 12-week, double-blind study.

**Important Warning and Precaution Regarding Metabolic Changes:**

Atypical antipsychotic drugs have been associated with metabolic changes that include:

- **Hyperglycemia/Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis, or hyperosmolar coma, or death, has been reported in patients treated with atypical antipsychotics including aripiprazole. Assess fasting plasma glucose before or soon after initiation of antipsychotic medication, and monitor periodically during long-term treatment.

- **Dyslipidemia:** Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.

- **Weight Gain:** Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
Data from aripiprazole tablet studies

4-WEEK TRIAL INCLUDING RISPERIDONE

Data from a 4-week, double-blind, placebo-controlled trial. Patients hospitalized with an acute exacerbation of schizophrenia or schizoaffective disorder (n=404) were randomized to receive aripiprazole (20 or 30 mg/day), risperidone (6 mg/day), or placebo. Risperidone was used as an active control in this study. The primary efficacy parameters were the change from baseline in PANSS Total Score, PANSS positive score, and CGI-S score to Week 4.*

4-WEEK TRIAL INCLUDING HALOPERIDOL

Data from a 4-week, double-blind, randomized, placebo-controlled trial. Patients hospitalized with an acute exacerbation of schizophrenia or schizoaffective disorder (n=414) were randomized to receive aripiprazole (15 or 30 mg/day), haloperidol (10 mg/day), or placebo. Haloperidol was used as an active control in this study. The primary efficacy variables were the mean change from baseline to Week 4 in PANSS Total Score, PANSS positive score, and CGI-S score.*

*This study was not designed to allow for comparison of aripiprazole and the active control.

Important Warning and Precaution Regarding Body Temperature Regulation:
Disruption of the body’s ability to reduce core body temperature has been attributed to antipsychotic agents. Advise patients regarding appropriate care in avoiding overheating and dehydration. Appropriate care is advised for patients who may exercise strenuously, may be exposed to extreme heat, receive concomitant medication with anticholinergic activity, or are subject to dehydration.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
Established efficacy of aripiprazole tablets in short-term trials

For your patients with schizophrenia

Both aripiprazole and haloperidol showed significant symptom improvement in PANSS Total Score

Both aripiprazole and risperidone showed significant symptom improvement in PANSS Total Score

Established efficacy of aripiprazole tablets in short-term trials

- Mean baseline PANSS Total Score: 94.4 (all patients)

- Mean baseline PANSS Total Score: 99.3 (all patients)

- Mean Change in PANSS Total Score From Baseline (LOCF)

- aP<0.01 vs placebo
- bP<0.001 vs placebo

LOCF=last observation carried forward;
PANSS=Positive and Negative Syndrome Scale.

Studies were not designed to allow for a comparison of aripiprazole and the active control.

Please see study designs on page 14.

Important Warning and Precaution Regarding Suicide:
The possibility of a suicide attempt is inherent in psychotic illnesses, and close supervision of high-risk patients should accompany drug therapy. Prescriptions for oral aripiprazole should be written for the smallest quantity consistent with good patient management in order to reduce the risk of overdose.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
In the treatment of patients with schizophrenia

Established safety of aripiprazole tablets in short-term trials

Adverse reactions in short-term clinical trials with aripiprazole tablets

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Preferred Term</th>
<th>Aripiprazole tablets (n=1843)</th>
<th>Placebo (n=1166)</th>
<th>Percentage of Patients Reporting Reaction(^a,b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Blurred Vision</td>
<td>3</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal Disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nausea</td>
<td>15</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Constipation</td>
<td>11</td>
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<td>Vomiting</td>
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<td>General Disorders and Administration Site Conditions</td>
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<td>Fatigue</td>
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<td>Musculoskeletal and Connective Tissue Disorders</td>
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<td>Muscle Spasms</td>
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Nervous System Disorders
- Headache: 27 vs. 23
- Dizziness: 10 vs. 7
- Akathisia: 10 vs. 4
- Sedation: 7 vs. 4
- Extrapyramidal Disorder: 5 vs. 3
- Tremor: 5 vs. 3
- Somolence: 5 vs. 3

Psychiatric Disorders
- Agitation: 19 vs. 17
- Insomnia: 18 vs. 13
- Anxiety: 17 vs. 13
- Restlessness: 5 vs. 3

Respiratory, Thoracic, and Mediastinal Disorders
- Pharyngolaryngeal Pain: 3 vs. 2
- Cough: 3 vs. 2

*Pooled incidence of adverse reactions (up to 6 weeks in schizophrenia and up to 3 weeks in bipolar mania) in patients treated with oral aripiprazole (doses ≥2 mg/day).

*Adverse reactions reported by at least 2% of patients treated with oral aripiprazole, except adverse reactions that had an incidence equal to or less than placebo.

Important Warning and Precaution Regarding Dysphagia:
Esophageal dysmotility and aspiration have been associated with aripiprazole; use caution in patients at risk for aspiration pneumonia.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
INDICATIONS and IMPORTANT SAFETY INFORMATION for ABILIFY® (aripiprazole) and ABILIFY MAINTENA® (aripiprazole)

INDICATIONS
ABILIFY® (aripiprazole) Tablets are an atypical antipsychotic indicated for the treatment of schizophrenia.
ABILIFY MAINTENA® (aripiprazole) is an atypical antipsychotic indicated for the treatment of schizophrenia.

IMPORTANT SAFETY INFORMATION

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS
Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk (1.6 to 1.7 times) of death compared to placebo (4.5% vs 2.6%, respectively). Although the causes of death were varied, most of the deaths appeared to be cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Aripiprazole is not approved for the treatment of patients with dementia-related psychosis.

Contraindication: Known hypersensitivity reaction to aripiprazole. Reactions have ranged from pruritus/urticaria to anaphylaxis.

Cerebrovascular Adverse Events, Including Stroke: Increased incidence of cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, have been reported in clinical trials of elderly patients with dementia-related psychosis treated with oral aripiprazole.

Neuroleptic Malignant Syndrome (NMS): A potentially fatal symptom complex sometimes referred to as NMS may occur with administration of antipsychotic drugs, including aripiprazole. Rare cases of NMS occurred during aripiprazole treatment. Signs and symptoms of NMS include hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (e.g., irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available.

Tardive Dyskinesia (TD): The risk of developing TD (a syndrome of abnormal, involuntary movements) and the potential for it to become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic increase. The syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. Prescribing should be consistent with the need to minimize TD. There is no known treatment for established TD, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

(Continued on next page.)

Please see FULL PRESCRIBING INFORMATION, including BOXED WARNING, for ABILIFY and ABILIFY MAINTENA in pocket.
Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that include:

- **Hyperglycemia/Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis, or hyperosmolar coma, or death, has been reported in patients treated with atypical antipsychotics including aripiprazole. Patients with diabetes should be regularly monitored for worsening of glucose control; those with risk factors for diabetes should undergo baseline and periodic fasting blood glucose testing. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

- **Dyslipidemia:** Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.

- **Weight Gain:** Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Pathological Gambling and Other Compulsive Behaviors: Intense urges, particularly for gambling, and the inability to control these urges have been reported while taking aripiprazole. Other compulsive urges (e.g., eating, sexual, or shopping) have been reported less frequently. Prescribers should ask patients or their caregivers specifically about, and closely monitor for, the development of new or intense compulsive urges. Consider dose reduction or stopping aripiprazole, if such urges develop.

Orthostatic Hypotension: Aripiprazole may cause orthostatic hypotension and should be used with caution in patients with known cardiovascular disease, cerebrovascular disease, or conditions which would predispose them to hypotension.

Falls: Antipsychotics may cause somnolence, postural hypotension, motor and sensory instability, which may lead to falls causing fractures or other injuries. For patients with diseases, conditions, or medications that could exacerbate these effects, complete fall risk assessments when initiating treatment and recurrently during therapy.

Leukopenia, Neutropenia, and Agranulocytosis: Leukopenia, neutropenia, and agranulocytosis have been reported. In patients with a history of clinically significant low white blood cell count (WBC)/absolute neutrophil count (ANC) or history of drug-induced leukopenia/neutropenia, perform a complete blood count (CBC) frequently during the first few months of therapy. Consider discontinuing aripiprazole at the first sign of a clinically significant decline in WBC in the absence of other causative factors. Monitor patients with clinically significant neutropenia for fever or other symptoms or signs of infection and treat promptly if such symptoms or signs occur. Discontinue aripiprazole in patients with severe neutropenia (ANC <1000/mm$^3$) and follow their WBC counts until recovery.

Seizures: Aripiprazole should be used with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

Potential for Cognitive and Motor Impairment: Aripiprazole may impair judgment, thinking, or motor skills. Instruct patients to avoid operating hazardous machinery, including automobiles, until they are certain aripiprazole does not affect them adversely.

(Continued on next page.)

Please see FULL PRESCRIBING INFORMATION, including BOXED WARNING, for ABILIFY and ABILIFY MAINTENA in pocket.
Body Temperature Regulation: Disruption of the body’s ability to reduce core body temperature has been attributed to antipsychotic agents. Advise patients regarding appropriate care in avoiding overheating and dehydration. Appropriate care is advised for patients who may exercise strenuously, may be exposed to extreme heat, receive concomitant medication with anticholinergic activity, or are subject to dehydration.

Suicide: The possibility of a suicide attempt is inherent in psychotic illnesses, and close supervision of high-risk patients should accompany drug therapy. Prescriptions for oral aripiprazole should be written for the smallest quantity consistent with good patient management in order to reduce the risk of overdose.

Dysphagia: Esophageal dysmotility and aspiration have been associated with aripiprazole; use caution in patients at risk for aspiration pneumonia.

Alcohol: Advise patients to avoid alcohol while taking aripiprazole.

Concomitant Medication

ABILIFY® (aripiprazole):

- Dosage adjustments are recommended in patients who are CYP2D6 poor metabolizers and in patients taking concomitant CYP3A4 inhibitors or CYP2D6 inhibitors or strong CYP3A4 inducers.
- When the coadministered drug is withdrawn from the combination therapy, ABILIFY dosage should then be adjusted to its original level. When the coadministered CYP3A4 inducer is withdrawn, ABILIFY dosage should be reduced to the original level over 1 to 2 weeks.
- For patients who are known CYP2D6 poor metabolizers, administer half of usual dose.
- For patients who are known CYP2D6 poor metabolizers taking concomitant strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin), administer a quarter of usual dose.
- For patients taking strong CYP2D6 (e.g., quinidine, fluoxetine, paroxetine) or CYP3A4 inhibitors (e.g., itraconazole, clarithromycin), administer half of usual dose.
- For patients taking strong CYP2D6 and CYP3A4 inhibitors, administer a quarter of usual dose.
- For patients taking strong CYP3A4 inducers (e.g., carbamazepine, rifampin), double usual dose over 1 to 2 weeks.

(Continued on next page.)
ABILIFY MAINTENA® (aripiprazole):
• Dosage adjustments are recommended in patients who are CYP2D6 poor metabolizers and in patients taking concomitant CYP3A4 inhibitors or CYP2D6 inhibitors for greater than 14 days.
• If the CYP3A4 inhibitor or CYP2D6 inhibitor is withdrawn, the ABILIFY MAINTENA dosage may need to be increased.
• Avoid the concomitant use of CYP3A4 inducers with ABILIFY MAINTENA for greater than 14 days because the blood levels of aripiprazole are decreased and may be below the effective levels.
• Dosage adjustments are not recommended for patients with concomitant use of CYP3A4 inhibitors, CYP2D6 inhibitors or CYP3A4 inducers for less than 14 days.

ABILIFY® (aripiprazole):
• Commonly Observed Adverse Reaction (≥5% incidence and at least twice the rate of placebo for ABILIFY vs placebo, respectively):
  o Adult patients with schizophrenia: Akathisia (8% vs 4%)

ABILIFY MAINTENA® (aripiprazole):
• Most Commonly Observed Adverse Reactions: Based on the placebo-controlled trial of ABILIFY MAINTENA in schizophrenia, the most commonly observed adverse reactions associated with the use of ABILIFY MAINTENA (incidence of 5% or greater and aripiprazole incidence at least twice that for placebo) were increased weight (16.8% vs 7.0%), akathisia (11.4% vs 3.5%), injection site pain (5.4% vs 0.6%), and sedation (5.4% vs 1.2%).
• Injection Site Reactions: In the data from the short-term, double-blind, placebo-controlled trial with ABILIFY MAINTENA in patients with schizophrenia, the percent of patients reporting any injection site-related adverse reaction (all reported as injection site pain) was 5.4% for patients treated with gluteal administered ABILIFY MAINTENA and 0.6% for placebo. In an open label study comparing bioavailability of ABILIFY MAINTENA administered in the deltoid or gluteal muscle, injection site pain was observed in both groups at approximately equal rates.

Dystonia: Symptoms of dystonia may occur in susceptible individuals during the first days of treatment and at low doses.

Pregnancy: Neonates exposed to antipsychotic drugs, including aripiprazole, during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms. These complications have varied in severity, from being self-limited to requiring intensive care and prolonged hospitalization. Aripiprazole should be used during pregnancy only if the potential benefits justify the potential risks to the fetus.

Lactation: Aripiprazole is present in human breast milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother and any potential risks to the infant.

To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).

Please see FULL PRESCRIBING INFORMATION, including BOXED WARNING, for ABILIFY and ABILIFY MAINTENA in pocket.
Dosing and Administration

Important Warning and Precaution Regarding Metabolic Changes:
Atypical antipsychotic drugs have been associated with metabolic changes that include:

- **Hyperglycemia/Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis, coma, or death, has been reported in patients treated with atypical antipsychotics including aripiprazole. Patients with diabetes should be regularly monitored for worsening of glucose control; those with risk factors for diabetes should undergo baseline and periodic fasting blood glucose testing. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

- **Dyslipidemia:** Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.

- **Weight Gain:** Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
Comparable doses related to oral aripiprazole

- ABILIFY MAINTENA 400 mg IM gluteal once monthly is similar to oral aripiprazole 20 mg/day
- ABILIFY MAINTENA 300 mg IM gluteal once monthly is similar to oral aripiprazole 15 mg/day

*The ABILIFY MAINTENA and oral aripiprazole modeling data were based on population pharmacokinetic simulations and provide an estimate of average steady state aripiprazole exposure.

<table>
<thead>
<tr>
<th>Comparable Doses*</th>
<th>ABILIFY MAINTENA†</th>
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<td>≈ 400 mg</td>
<td>20 mg per day</td>
</tr>
<tr>
<td>300 mg once monthly</td>
<td>≈ 300 mg</td>
<td>15 mg per day</td>
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400 mg of ABILIFY MAINTENA delivers 400 mg of aripiprazole.

300 mg of ABILIFY MAINTENA delivers 300 mg of aripiprazole.

For patients naïve to aripiprazole, establish tolerability with oral aripiprazole prior to initiating ABILIFY MAINTENA. Due to the half-life of oral aripiprazole, it may take up to 2 weeks to fully assess tolerability.

† The labeled strengths are calculated based on the anhydrous form (aripiprazole).

Important Warning and Precaution Regarding Concomitant Medication:
Dosage adjustments are recommended in patients who are CYP2D6 poor metabolizers and in patients taking concomitant CYP3A4 inhibitors or CYP2D6 inhibitors for greater than 14 days. If the CYP3A4 inhibitor or CYP2D6 inhibitor is withdrawn, the ABILIFY MAINTENA dosage may need to be increased. Avoid the concomitant use of CYP3A4 inducers with ABILIFY MAINTENA for greater than 14 days because the blood levels of aripiprazole are decreased and may be below the effective levels. Dosage adjustments are not recommended for patients with concomitant use of CYP3A4 inhibitors, CYP2D6 inhibitors or CYP3A4 inducers for less than 14 days.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
Picture ABILIFY MAINTENA® (aripiprazole) for schizophrenia treatment

Keeps blood concentrations of aripiprazole within therapeutic levels throughout the month

STUDY DESIGN
Open-label Phase 1b study to assess the safety, tolerability, effectiveness, and pharmacokinetics of ABILIFY MAINTENA administered by gluteal intramuscular injection to patients* with schizophrenia.22

• Mean steady-state plasma concentration range for once-monthly ABILIFY MAINTENA 400 mg (n=12) was within the concentration range for multiple, consecutive daily doses (14 days) of oral aripiprazole 10 mg to 30 mg22-24

• Following multiple doses, there is a gradual rise of aripiprazole to maximum plasma concentrations (Tmax) at a median of 4 days for the deltoid muscle and 5 to 7 days for the gluteal muscle

Important Warning and Precaution Regarding Alcohol:
Advise patients to avoid alcohol while taking aripiprazole.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
Options for dosing and administration

RECOMMENDED STARTING AND MAINTENANCE DOSE

• 400 mg single injection administered monthly
• Along with the first injection of ABILIFY MAINTENA, treatment with oral aripiprazole (10 mg to 20 mg) or current oral antipsychotic should be continued for 14 consecutive days
• For patients who have never taken aripiprazole, establish tolerability with oral aripiprazole prior to initiating treatment with ABILIFY MAINTENA. Due to the half-life of oral aripiprazole, it may take up to 2 weeks to fully assess tolerability
• ABILIFY MAINTENA should not be administered sooner than 26 days after previous injection
• Consider reducing to 300 mg in patients with adverse reactions

DOSAGE ADJUSTMENTS

• Dosage adjustments are required for missed doses
• Dosage adjustments are recommended for patients who are CYP2D6 poor metabolizers and in patients taking concomitant CYP3A4 inhibitors or CYP2D6 inhibitors for more than 14 days
• Avoid concomitant use of CYP3A4 inducers with ABILIFY MAINTENA for more than 14 days

ADMINISTRATION

• Pre-filled dual chamber syringe or vial kits are available
• Choice of deltoid or gluteal IM administration
• Only for administration by a healthcare professional

IM=intramuscular.

For additional dosage and administration information, please see FULL PRESCRIBING INFORMATION, including BOXED WARNING, in pocket.

Most Commonly Observed Adverse Reactions:
Based on the placebo-controlled trial of ABILIFY MAINTENA in schizophrenia, the most commonly observed adverse reactions associated with the use of ABILIFY MAINTENA (incidence of 5% or greater and aripiprazole incidence at least twice that for placebo) were increased weight (16.8% vs 7.0%), akathisia (11.4% vs 3.5%), injection site pain (5.4% vs 0.6%), and sedation (5.4% vs 1.2%).

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
Flexibility in administration

- Pre-filled dual chamber syringe reduces the number of steps required for reconstitution compared with the vial kit
- Administer within 30 minutes after reconstituting pre-filled dual chamber syringe
- Vial kits provide the flexibility to choose doses in amounts other than 400 mg or 300 mg in patients requiring dosage adjustments
- Both the pre-filled dual chamber syringe and vials are stored at room temperature*
- Along with the first injection, patients should also receive a prescription for oral aripiprazole (10 mg to 20 mg) or current oral antipsychotic for 14 consecutive days
- Please specify either the pre-filled dual chamber syringe or the vial kit when writing either an electronic or a conventional prescription
- All doses can be given by deltoid or gluteal intramuscular administration (see page 24 for dosing)

*Pre-filled dual chamber syringe: Store below 30°C (86°F). Do not freeze. Protect the syringe from light by storing in the original package until time of use. Vial: Store at 25°C (77°F); excursions permitted between 15°C and 30°C (59°F to 86°F). [See USP Controlled Room Temperature.]

Important Warning and Precaution Regarding Injection Site Reactions:
In the data from the short-term, double-blind, placebo-controlled trial with ABILIFY MAINTENA in patients with schizophrenia, the percent of patients reporting any injection site-related adverse reaction (all reported as injection site pain) was 5.4% for patients treated with gluteal administered ABILIFY MAINTENA and 0.6% for placebo. In an open label study comparing bioavailability of ABILIFY MAINTENA administered in the deltoid or gluteal muscle, injection site pain was observed in both groups at approximately equal rates.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
For patients with schizophrenia

Discharge planning
Considerations for psychiatric discharge planning

Information presented here is from a 2012 review article that aimed to locate different levels of evidence in discharge planning.

— The authors of the article sought to summarize the findings for clinicians involved in psychiatric discharge planning.

*The reliability and validity of this discharge plan have not yet been determined.

**INITIATION OF PLAN**
- Establishing patient/treatment team collaboration
- Formulating a discharge plan and risk and relapse plan relating to the specific needs of the patient

**CONFIRMING ACCESS TO AFTERCARE**
- Determining the level of support and assistance that are necessary to help the patient live in the community setting

**IN Volving patient and caregiver**
- Having the patient and caregiver participate in the discharge plan, where possible

**Reviewing the plan**
- Confirming the patient understands and agrees with the discharge plan, including treatment and follow-up care
Important Warning and Precaution Regarding Dystonia:
Symptoms of dystonia may occur in susceptible individuals during the first days of treatment and at low doses.

*In a 12-week study. N=340 randomized. † See clinical study information on pages 6, 7, 8, 12, and 13.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
Consider the benefits of the treatNOW starter program

The treatNOW starter program is intended to provide starter program kits, free of charge, to qualified, licensed healthcare providers who, in their independent medical judgment, determine that immediate onsite treatment of their patient with a diagnosis within the product’s approved label is medically warranted. These starter program kits are not for sale, resale, trade or barter, and healthcare providers may not bill any third-party payer for starter program kits received through the treatNOW starter program.

Provides timely treatment for your patients.

Helps meet a variety of dosing needs with kit options that now include aripiprazole tablets.

Helps facilitate successful initiation with useful support materials.

STARTER KIT OPTIONS ARE AVAILABLE TO HELP MEET THE NEEDS OF YOUR PATIENTS

ABILIFY MAINTENA® (aripiprazole) 400 mg pre-filled, dual chamber syringe (DCS), an all-in-one delivery system that offers fewer steps in the reconstitution process.

ABILIFY MAINTENA 400 mg vial kit for patients requiring dosage adjustments.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
Important Warning and Precaution Regarding Metabolic Changes:
Atypical antipsychotic drugs have been associated with metabolic changes that include:

• **Hyperglycemia/Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis, coma, or death, has been reported in patients treated with atypical antipsychotics including aripiprazole. Patients with diabetes should be regularly monitored for worsening of glucose control; those with risk factors for diabetes should undergo baseline and periodic fasting blood glucose testing. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

• **Dyslipidemia:** Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.

• **Weight Gain:** Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.
ABILIFY MAINTENA® (aripiprazole) has broad national access

ABILIFY MAINTENA is available through Medicare Part D (M-PDP, MA-PDP), FFS Medicaid, Managed Medicaid, and commercial/private payers.

**ABILIFY MAINTENA COVERAGE TYPE**

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<th>COVERED AS BOTH PHARMACY AND MEDICAL BENEFIT</th>
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This resource is provided for informational purposes only, and does not guarantee that billing codes will be appropriate or that coverage and reimbursement will result. Providers should consult with their payers for all relevant coverage, coding, and reimbursement requirements. It is the sole responsibility of the provider to select proper codes and ensure the accuracy of all claims used in seeking reimbursement. This resource is not intended as legal advice or as a substitute for a provider’s independent professional judgment.

*Table values represent percentage of covered lives by payer type. National percentages are representative of total market lives across all payer types.

†Certain healthcare payers may require prior authorization or a trial with another medication before ABILIFY MAINTENA can be initiated.

‡As a non–self-administered injectable medication, certain payers require reimbursement through a medical claims (ie, medical benefit) process.

FFS=fee-for-service.


**Important Warning and Precaution Regarding Pregnancy:**

Neonates exposed to antipsychotic drugs, including aripiprazole, during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms. These complications have varied in severity, from being self-limited to requiring intensive care and prolonged hospitalization. Aripiprazole should be used during pregnancy only if the potential benefits justify the potential risks to the fetus.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.

**IMPORTANT SAFETY INFORMATION** on pages 17-20.

**WARNING:** INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

ABILIFY MAINTENA® (aripiprazole) is an atypical antipsychotic indicated for the treatment of schizophrenia.

**INDICATION**

ABILIFY MAINTENA® (aripiprazole) is an atypical antipsychotic indicated for the treatment of schizophrenia.

**WARNING:** INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk (1.6 to 1.7 times) of death compared to placebo (4.5% vs 2.6%, respectively). Although the causes of death were varied, most of the deaths appeared to be cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Aripiprazole is not approved for the treatment of patients with dementia-related psychosis.

Please see IMPORTANT SAFETY INFORMATION on pages 17-20.