COVER SHEET

This page is provided as a guide / fax cover sheet and is not required for enrollment

FAX OR MAIL COMPLETED FORMS

Fax: 1 (855) 876-2627

Mail: PO Box 220684, Charlotte, NC, 28222-0684

Questions? Call 1 (855) 999-2627

Need help completing the form? Visit http://ASSURE.com/HCP/AbilifyMaintena/ for downloadable forms and instruction guide

IMPORTANT INSTRUCTIONS

- **Please ensure that all necessary information is provided (fields in gray are optional)**
- **You may complete each section or provide copies of face sheets, insurance cards and prescriptions with the necessary information**
- **Please ensure that prescriber and patient signatures are obtained for all applications**
- **If the patient is uninsured and would like to also be reviewed for Patient Assistance, please complete the Patient Assistant Program Enrollment Form (last two pages of this file)**

Page 1: Prescriber and prescription information

Complete **prescriber information** and facility address

Provide a **facility primary contact** in case we have questions about this form

Complete or attach **prescription**

Please provide the **primary diagnosis code** for benefits verification and patient assistance

Prescriber signature required for all applications

Page 2: Insurance information and program offerings

If patient has more than one insurance plan, please include both (copies of insurance cards are accepted)

Please provide contact information for the follow-up care provider, if different from prescriber

Page 3: Patient authorizations

Please select relevant authorizations

Patient signature required if any authorizations are selected

Please **CLICK HERE** for Full Prescribing Information for Abilify Maintena® (aripiprazole), including **Boxed WARNING** about INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS, and please see the Indication and Important Safety Information on page 4.

Patient Enrollment Form for Abilify Maintena® (aripiprazole)

ASSURE™

Fax completed forms to: 1 (855) 876-2627
Phone: 1 (855) 999-2627 | Address: PO Box 220684, Charlotte, NC, 28222-0684

1. PRESCRIBER INFORMATION

Prescriber Name: License #: State Licensed:

Facility Address: Tax ID #: NPI #:

City: State: Zip: Phone: ( ) - Fax: ( ) -

Facility name: Email:

Facility primary contact: Alt. Contact Name:

Contact Phone: ( ) - Alt. Contact Phone: ( ) -

2. PATIENT INFORMATION

First: MI: Last: Phone: ( ) -

Gender: M F DOB: SSN: Cell: ( ) -

Address: City: State: Zip:

Alternate Patient Contact (optional)

The below contact information will be used to coordinate care support if the patient cannot be reached or is unable to manage his/her care. Examples of alternate patient contacts include, but are not limited to, caregivers, guardians, and conservators. Please see page 3 for Patient Authorization.

Name: Phone: ( ) -

Relationship to Patient:

3. PRESCRIPTION INFORMATION & PRESCRIBER AUTHORIZATION

Support will only be provided for patients whose prescription is consistent with an FDA-approved indication.

Primary Diagnosis Code:
(ICD-9 and ICD-10 codes listed, see page 4 for code descriptions)

295.0/F20.89 295.1/F20.1 295.2/F20.2 295.3/F20.0

295.5/F20.89 295.6/F20.5 295.8/F20.89 295.9/F20.3 or F20.9

Other

Prescribed dose of ABILIFY MAINTENA® (aripiprazole):

Dosage: Prefilled dual chamber Vial kit

Quantity: Refills:

Directions:

I certify that the treatment listed above is and will be medically necessary based on my best professional judgment and that the information provided in this form is complete and accurate to the best of my knowledge. I also certify that I have obtained patient consent for the disclosure of protected health information (PHI) as required by the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"), and any other legally required consents of the patient (or the patient's legal representative) for the release of the patient's information to the ASSURE Program (the "Program") and Otsuka America Pharmaceutical, Inc. and/or its representatives or agents (collectively, "OAPI"), as may be necessary for the patient's participation in the Program and for the Program and OAPI to use and disclose such information as necessary to provide reimbursement support and other related information and resources to me and my patient in connection with the patient's therapy. I attest that I am not on the HHS/OIG list of Excluded Individuals and that I am authorized under State law to prescribe and dispense the requested medication. I authorize and appoint the Program and OAPI to convey on my behalf any prescription information delivered to the Program to the dispensing pharmacy chosen by or for the patient. I understand that the Program and OAPI will use and disclose this information only in connection with the Program, including but not limited to performing a preliminary verification of the patient's insurance coverage for ABILIFY MAINTENA® (aripiprazole) and triage to OAPI's Patient Assistance Program ("PAP") if applicable, and as otherwise required or permitted by law. I further certify that (a) any support provided through the Program on behalf of any patient is not made in exchange for any express or implied agreement or understanding that I would recommend, prescribe, or use ABILIFY MAINTENA® (aripiprazole) or any other OAPI product or service, and (b) my decision to prescribe ABILIFY MAINTENA® (aripiprazole) was based on my determination of medical necessity as set forth herein. I agree that the Program and OAPI may contact me for additional information relating to the Program or ABILIFY MAINTENA® (aripiprazole), including but not limited via email, fax and telephone. I understand that OAPI reserves the right, at any time and without notice, to modify or discontinue the Program. I understand that completing this enrollment form does not ensure that the patient will obtain insurance coverage or reimbursement for my prescription, and that any support provided through the Program are provided for information purposes only and represent no statement, promise or guarantee by the Program or OAPI. I agree that in no event shall OAPI be liable for any damages resulting from or relating to the Program. I am directing the retail pharmacy selected by my patient to administer the pharmaceutical product I have indicated.

Sign Here ✖

Prescriber's Signature (required) Printed Name Date

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Patient Enrollment Form for Abilify Maintena® (aripiprazole)

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4. INSURANCE INFORMATION

ATTACH A COPY OF BOTH SIDES OF THE PATIENT'S INSURANCE CARD(S). IF NOT AVAILABLE, PLEASE COMPLETE BELOW.

Primary Insurance

Plan Name: Policy #: Group #:

Policy Holder DOB: Policy Holder (or relationship): Insurance Phone: ( ) -

Secondary Insurance

Plan Name: Policy #: Group #:

Policy Holder DOB: Policy Holder (or relationship): Insurance Phone: ( ) -

Prescription Plan (IF PATIENT HAS SEPARATE PRESCRIPTION COVERAGE, PLEASE COMPLETE)

Plan Name: Policy #: Group #:

Policy Holder DOB: Policy Holder (or relationship): Insurance Phone: ( ) -

BIN: PCN:

5. PROGRAM OFFERINGS

CHECK THE OFFERINGS YOU WOULD LIKE FOR YOUR PATIENT

Benefits verification, prior authorization support, and co-pay savings, if applicable

Patient assistance program (please complete the Patient Assistance Program Enrollment Form (last two pages of this file) if requesting this offering)

ASSURE Navigator transition/reminder support

ASSURE Navigators are nurses who can provide patients and caregivers with dedicated support via telephone. Navigators aid patients with such things as scheduling treatment appointments, providing reminder and follow-up calls, and supplying information on external community support resources. Navigators do not provide medical advice. Additional details on page 3.

Where will the patient receive follow-up care? Please complete below if <u>different</u> from Prescriber Information in Section 1:

Provider Name: NPI: License #:

Facility Name: Phone: ( ) - Fax: ( ) -

Address: City: State: Zip:

Facility Staff Name: Phone: ( ) -

Connections to Local Care Centers

Local care centers are retail pharmacies that may offer convenient locations for your patient to receive their treatment. At these pharmacies, licensed healthcare professionals are trained to administer injections. This offering is currently available in select markets in CA, TX, PA, and WA.

I would like to receive information concerning LCCs near: **Next injection due by:**

Patient's home address Prescriber's office address Date _____

Please **CLICK HERE** for Full Prescribing Information for Abilify Maintena® (aripiprazole), including **Boxed WARNING** about INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS, and please see the Indication and Important Safety Information on page 4.

Otsuka

Patient Enrollment Form for Abilify Maintena® (aripiprazole)

ASSURE™

Fax completed forms to: 1 (855) 876-2627
Phone: 1 (855) 999-2627 | Address: PO Box 220684, Charlotte, NC, 28222-0684

6. PATIENT AUTHORIZATION

Local care center

I would like to receive information about local care center ("LCC") locations which are independently-operated retail pharmacies that can administer Abilify Maintena® (aripiprazole). I attest that I need to receive treatment in an LCC location, as opposed to an office or a hospital. I understand that the ASSURE Program will provide information to allow me to, in consultation with my physician, decide my best treatment location, but will not make the decision for me. I also understand that the ASSURE Program will connect me with an LCC to administer my treatment, and that neither Otsuka nor the ASSURE Program will be providing my treatment. Lastly, I understand that if I choose to receive treatment at an LCC, the LCC will obtain my medical or health information in order to administer treatment to me.

ASSURE Navigator

I would like to receive periodic contact from an ASSURE Navigator for purposes such as checking my progress, setting reminders for my next injection and other services. ASSURE Navigators do not provide medical advice, and I will continue to direct my treatment-related questions to my physician. The ASSURE Navigator will contact me for my contact information, to determine how I'd like to be contacted (ie, via phone, email, text, etc.), and for the preferred days and times of the week I'd like to be contacted. I understand that I can stop future communications from this program at any time by calling 1 (855) 999-2627 or by mailing a signed written statement of my revocation to PO Box 220684, Charlotte NC 28222-0684. In addition, if I have provided an alternate patient contact on page 1, I give the ASSURE Navigator permission to contact my alternate patient contact for purposes such as discussing my treatment, reviewing updates about my health status, and assessing my ongoing needs related to my therapy. The ASSURE Navigator will call my alternate patient contact to determine how he/she would like to be contacted (ie, via phone, email, text, etc.), and preferred days and times of the week for contact.

I authorize my healthcare provider, health insurer, pharmacist and other relevant third parties to disclose to Otsuka America Pharmaceutical, Inc. ("OAPI") and/or its agents (collectively, OAPI), and OAPI to use, my protected health information, including but not limited to insurance information, diagnosis, prescriptions and my city and state (together my "Protected Health Information") for purposes of internal data collection and analytic efforts. I understand that I can stop future sharing of my Protected Health Information for data collection and analytics purposes at any time by calling 1 (855) 999-2627 or by mailing a signed written statement of my revocation to PO Box 220684, Charlotte NC 28222-0684. I understand that revoking this authorization will prohibit disclosures after the date revocation is received, except to the extent that action has already been taken in reliance on this authorization.

I understand that OAPI or approved parties acting on its behalf may use the information I am providing to send me information and offers that may be interest to me. OAPI will not sell or transfer my information to any third parties. I understand that from time to time OAPI's privacy policy may change and that I should check OAPI's web site for the most recent version of the privacy policy. I can request to stop receiving OAPI marketing communications by calling 1 (855) 6-ASSURE or by going to the following website www.abilifymaintena.com/unsubscribe.

I understand that:

- This authorization is entirely optional. I may decline to provide this authorization and still participate in the Otsuka Patient Assistance Program. My healthcare providers will not condition my medical treatment on my agreement to provide this authorization.
- This authorization will continue indefinitely until I revoke it as described above.
- Once my Protected Health Information is released based on this authorization, Federal and State privacy laws may not prevent the entities described above from re-disclosing my Protected Health Information, although they have agreed to only use or disclose information received for purposes described in this authorization or as otherwise permitted or required by law.
- I can request a copy of this authorization.

Sign Here ✖

Patient or Legal Authorized representative Printed Name Year of Birth Date

DIAGNOSIS CODE DESCRIPTIONS

ICD-9/ICD-10 Code	Description	ICD-9/ICD-10 Code	Description
295.0/F20.89	Simple type schizophrenia	295.5/F20.89	Latent schizophrenia
295.1/F20.1	Disorganized type schizophrenia	295.6/F20.5	Schizophrenic disorder, residual type
295.2/F20.2	Catatonic type schizophrenia	295.8/F20.89	Other specified types of schizophrenia
295.3/F20.0	Paranoid type schizophrenia	295.9/F20.3 or F20.9	Unspecified/undifferentiated schizophrenia

INDICATION and IMPORTANT SAFETY INFORMATION for Abilify Maintena® (aripiprazole)
for extended-release injectable suspension

INDICATION

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). Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. 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. Abilify Maintena 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 dementiarelated psychosis treated with oral aripiprazole.

Neuroleptic Malignant Syndrome (NMS): A potentially fatal symptom complex sometimes referred to as NMS may occur with administration of anti-psychotic drugs, including Abilify Maintena. 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, athough the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

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. Clinical monitoring of weight is recommended.

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

Leukopenia, Neutropenia, and Agranulocytosis: Leukopenia, neutropenia, and agranulocytosis have been reported. Patients with a history of clinically significant low white blood cell (WBC) count or drug-induced leukopenia/neutropenia should have their complete blood count monitored frequently during the first few months of therapy while receiving Abilify Maintena. In such patients, consider discontinuation of Abilify Maintena at the first sign of a clinically significant decline in WBC count in the absence of other causative factors.

Seizures/Convulsions: Abilify Maintena 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: Abilify Maintena may impair judgment, thinking, or motor skills. Instruct patients to avoid operating hazardous machinery including automobiles until they are certain Abilify Maintena does not affect them adversely.

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.

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

Alcohol: Advise patients to avoid alcohol while taking Abilify Maintena.

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.

Most commonly observed adverse reaction: Based on the placebo-controlled trial of Abilify Maintena in schizophrenia, the most commonly observed adverse reactions associated with the use of aripiprazole (incidence of 5% of 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.

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

Pregnancy/Nursing: Based on animal data, may cause fetal harm. Abilify Maintena should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. 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.

Please see [accompanying] FULL PRESCRIBING INFORMATION, including **Boxed WARNING**, for Abilify Maintena.

Please **CLICK HERE** for Full Prescribing Information for Abilify Maintena® (aripiprazole), including **Boxed WARNING** about INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

COVER SHEET

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FAX OR MAIL COMPLETED FORMS

Fax: 1 (844) 727-6274 **Mail:** PO Box 222065, Charlotte, NC 28222-2065

Questions? Call Otsuka Patient Assistance Program at 1 (855) 727-6274

INSTRUCTIONS FOR PATIENT ASSISTANCE PROGRAM COMPLETION

Complete PATIENT INSURANCE INFORMATION

Patient's household size and annual household income required for patient assistance

Patient or Legal Authorized Representative's signature is required

Patient Assistance Program Enrollment Form for Abilify Maintena® (aripiprazole)

ASSURE™

FAX COMPLETED FORMS TO 1 (844) 727-6274 | Phone: 1 (855) 727-6274

1. PATIENT INSURANCE INFORMATION

First: MI: Last: Phone: ( ) -

Gender: M F DOB: SSN: Cell: ( ) -

Does the patient have insurance or any prescription drug coverage?	Yes	No
Is the patient enrolled in Medicare, Medicaid, VA, or TRICARE?	Yes	No
If no to above, has patient applied for Medicare, Medicaid, VA, or TRICARE?	Yes	No
Is patient a United States citizen or resident?	Yes	No

Patient's annual household income $ _____ Household size, including patient: _____

2. CERTIFICATION AND AUTHORIZATION TO DISCLOSE INFORMATION

The patient, or the patient's authorized representative, MUST sign this form to receive product at no cost from the Otsuka Patient Assistance Program ("PAP"). Before signing, you, the patient or an authorized representative, should review, understand, and agree to the terms of this authorization and release. If you are an authorized representative signing for the patient, please indicate your relationship to the patient.

I verify that the information provided on this form is true and correct.

I will immediately inform the Otsuka PAP and my healthcare provider if my income or insurance status changes while I am receiving help from the PAP.

I authorize my healthcare provider, health insurer, pharmacist and other relevant third parties to disclose to Otsuka America Pharmaceutical, Inc. ("OAPI") and/or its agents (collectively, OAPI), and OAPI to use, my protected health information, including but not limited to insurance information, diagnosis, prescriptions and my city and state (together my "Protected Health Information") for the purposes of administering the program. This includes investigating and resolving coverage, coding, or reimbursement inquiries, administering the Otsuka PAP, coordinating the delivery of product for my treatment, and determining if I am eligible for health insurance coverage or other funds.

I understand that:

- Application to the Otsuka PAP does not guarantee assistance.
- Participation in the Otsuka PAP is subject to approval under program guidelines.
- Approval is for a limited period.
- Periodic re-application is required for continued participation.
- My healthcare providers will not condition my medical treatment on my agreement to sign this Patient Authorization and Release.
- Once information about me is released based on this authorization, Federal and State privacy laws may not prevent the entities described above from re-disclosing my information, although they have agreed to only use or disclose information received for the purposes described in this authorization or as otherwise permitted or required by law.
- This authorization will remain in effect for one (1) year unless revoked earlier.
- I can cancel this authorization at any time by faxing a signed written statement of my cancellation to 1 (844) 727-6274 (1-844-PAP-OAPI), but this would end my eligibility to participate in the Otsuka PAP. Canceling this authorization will prohibit disclosures after the date written revocation is received, but not action that has already been taken by relying on this authorization. This means that, after I revoke this authorization, my information may be disclosed among OAPI and companies that help OAPI administer the programs in order to maintain records of my participation, but it will not be otherwise disclosed or used without my written consent.
- OAPI reserves the right at any time and without notice to modify or change eligibility criteria, or modify or discontinue the Otsuka PAP.
- I can request a copy of this form.

I authorize my insurer, doctor, healthcare provider, and pharmacist to:

- Release information about my prescribed medications and medical condition requested by OAPI;
- Disclose any information obtained from the sources listed above to third parties if required or otherwise permitted by law.

Sign Here ✖

Patient or Legal Authorized Representative's signature Year of Birth Date

Printed Name Relationship to Patient

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