DEPARTMENT OF HEALTH SERVICES
Division of Care and Treatment Services
F-24277 (05/2024)

STATE OF WISCONSIN
42 CFR483.420(a)(2)
DHS 134.31(3)(o)
DHS 94.03 & 94.09
§§ 51.61(1)(g) & (h)

INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 08/19/2020

Completion of this form is voluntary. If informed consent is not given, the medication cannot be administered without a court order unless in an emergency.
This consent is maintained in the client's record and is accessible to authorized users.

Name – Patient / Client (Last, First MI)	ID Number	Living Unit	Date of Birth
,			

Name – Individual Preparing This Form	Name – Staff Contact	Name / Telephone Number – Institution

MEDICATION CATEGORY	MEDICATION	RECOMMENDED DAILY TOTAL DOSAGE RANGE	ANTICIPATED DOSAGE RANGE
Antipsychotic Antidepressant Bipolar/Mood Stabilizing Agent	Abilify, Abilify Maintena, Abilify MyCite, Aristada, Aristada Initio (aripiprazole)	Abilify Tablet: 2 mg -30 mg Abilify Oral Solution: 30 mg Abilify MyCite Tablet: 2 mg-30 mg Long Acting Injection: *Abilify Maintena* (300 mg-400 mg IM every 4 weeks) *Aristada* (441 mg-662 mg IM every 4 weeks, 882 mg IM every 4-6 weeks, 1064 mg every 8 weeks) *Aristada Initio* (675 mg)	

The anticipated dosage range is to be individualized, may be above or below the recommended range but no medication will be administered without your informed and written consent.
Recommended daily total dosage range of manufacturer, as stated in *Physician's Desk Reference* (PDR) or another standard reference.
This medication will be administered ☐ Orally ☐ Injection ☐ Other – Specify:

1. Reason for Use of Psychotropic Medication and Benefits Expected (note if this is 'Off-Label' Use)
Include DSM-5 diagnosis or the diagnostic impression ("working hypothesis.")

2. Alternative mode(s) of treatment other than OR in addition to medications include
Note: Some of these would be applicable only in an inpatient environment.

☐ Environment and/or staff changes
☐ Positive redirection and staff interaction
☐ Individual and/or group therapy
☐ Rehabilitation treatments/therapy (OT, PT, AT)
☐ Treatment programs and approaches (habilitation)
☐ Use of behavior intervention techniques

Other Alternatives:

3. Probable consequences of NOT receiving the proposed medication are

Impairment of ☐ Work Activities ☐ Family Relationships ☐ Social Functioning

Possible increase in symptoms leading to potential

☐ Use of seclusion or restraint
☐ Limits on access to possessions
☐ Limits on personal freedoms
☐ Limit participation in treatment and activities
☐ Limits on recreation and leisure activities
☐ Intervention of law enforcement authorities
☐ Risk of harm to self or others

Other Consequences:

Note: These consequences may vary depending upon whether or not the individual is in an inpatient setting. It is also possible that in unusual situations, little or no adverse consequences may occur if the medications are not administered.

See Page 2

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4. Possible side effects, warnings, and cautions associated with this medication are listed below. This is not an all-inclusive list but is representative of items of potential clinical significance to you. For more information on this medication, you may consult further with your physician or refer to a standard text, such as the PDR. As part of monitoring some of these potential side effects, your physician may order laboratory or other tests. The treatment team will closely monitor individuals who are unable to readily communicate side effects in order to enhance care and treatment.

Continued – Possible side effects, warnings, and cautions associated with this medication.

Most Common Side Effects: increased cholesterol; weight gain; having a sense of inner restlessness or feeling like you cannot sit still; headache; constipation; nausea; dizziness; increased glucose; rash; anxiety; fatigue; tremor; vomiting.

Less Common Side Effects: bloating or swelling of face, arms, hands, lower legs, or feet; blurry vision; body aches or pain; airway congestion; coughing; difficulty with movement; fever; increased salivation- drooling (children); joint pain; muscle aching or cramping; muscle stiffness; stuffy nose (children); swollen joints; trouble swallowing; unusual weight gain or loss; acid or sour stomach; belching; dry mouth; fear; irregular heartbeat; irritability; loss of strength; lightheadedness; nervousness; sleepiness or unusual drowsiness; difficulty falling asleep or staying asleep; stomach discomfort, upset, or pain; back pain; increased risk of upper respiratory tract infections; bloody nose; loss of bladder control; orthostatic hypotension (dizziness or lightheadedness when standing from a seated or lying position).

Rare Side Effects: Although rare, please call your doctor as soon as possible if any of the following side effects occur: difficulty speaking; loss of balance control; muscle trembling, jerking, or stiffness; shuffling walk; severe muscle stiffness; twisting movements of body; uncontrolled movements, especially of face, neck, and back; worsening of behavior; increased need to urinate; seizures or convulsions; difficulty in breathing; fast heartbeat; high fever; high or low blood pressure; excessive sweating; lip smacking or puckering; puffing of cheeks; rapid or worm-like movements of tongue; sudden loss of consciousness; extreme fatigue; uncontrolled chewing movements; uncontrolled movements of arms and legs; unusually pale skin; changes to menstruation; swelling of face, tongue, or throat; difficulty achieving erection; hair loss; blood coagulation disorders; generalized skin itch; loss of sexual desire or function; chest pain; heart fluttering; double vision; suicidal thoughts or actions (if you do experience this, please call your doctor immediately); yellowing of the skin or eyes.

Caution

- **Extrapyramidal symptoms (EPS)**
  Patients have reported muscle spasms of the neck and back; shuffling walk; tic-like (jerky) movements of the head, face and neck; trembling and shaking of the hands and fingers; inability to move eyes; mask-like face; loss of balance control; blurred vision; difficulty speaking or swallowing. Additionally, though not common, Tardive Dyskinesia has been reported. Tardive Dyskinesia presents with lip smacking or puckering, puffing of cheeks, rapid or fine worm-like movement of tongue, uncontrolled chewing movement, or uncontrolled movements of arms and legs may occur and may not go away after stopping use of the medication.
- **Neuroleptic Malignant Syndrome (NMS)**
  Use may be associated with NMS. Monitor for changes in thinking, fever, muscle stiffness, and/ or autonomic instability (unable to exercise, abnormal sweating, loss of appetite, loss of bladder control, difficulty with ejaculation, burry vision). Call your doctor as soon as possible if you believe you may have NMS.
- **Driving and operating heavy machinery**
  Aripiprazole may cause drowsiness or dizziness, which could make driving, operating heavy machinery, or participating in other activities requiring alertness dangerous. Be sure you know how this medication affects you before participating in these activities.
- **Blood disorder**
  Check with your doctor immediately if you develop fever, chills, sore throat, or sores in the mouth. These may be signs of a very serious blood problem that has occurred rarely in patients taking aripiprazole. This medication also has the potential to increase bleeding.
- **Orthostatic hypotension**
  Orthostatic hypotension is when one feels dizzy while standing up from a lying or sitting position. Getting up slowly may help. If this problem continues or gets worse, check with your doctor.
- **Fall risk**
  This medication increases the risk of experiencing a fall due to drowsiness and dizziness. Caution should be exercised by those who have a history of falls.
- **Weight gain**
  This medication has been associated with increased appetite and weight gain.
- **Seizure**
  This medication may, in rare cases, cause a seizure. Caution should be exercised in those who have a history of seizures.
- **Withdrawal**
  This medication should not be suddenly stopped as doing so may cause an individual to experience symptoms of withdrawal. Please speak with your physician before stopping this medication.

Client Initial _____ Date _____

Medication: Abilify; Abilify Maintena: Aristada (aripiprazole)

Warning: [Black Box Warning]: Increased Mortality in Elderly Patients with Dementia Related Psychosis:
Elderly patients with dementia related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of 17 placebo controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipyschotic drugs, revealed a risk of death in the drug treated patients of between 1.6 to 1.7 times that seen 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 either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. Aripiprazole is not approved for the treatment of patients with dementia-related psychosis.

Warning: [Black Box Warning]: Suicidality and Antidepressant Drugs:
Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of adjunctive Abilify or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Abilify is not approved for use in pediatric patients with depression.

See standard reference text for an all-inclusive list of side effects.

By my signature below, I GIVE consent for the named medication on Page 1 and anticipated dosage range. My signature also indicates that I understand the following:

1. I can refuse to give consent or can withdraw my consent at any time with written notification to the institution director or designee. This will not affect my right to change my decision at a later date. If I withdraw consent after a medication is started, I realize that the medication may not be discontinued immediately. Rather, it will be tapered as rapidly as medically safe and then discontinued so as to prevent an adverse medical consequence, such as seizures, due to rapid medication withdrawal.
2. Questions regarding this medication can be discussed with the Interdisciplinary Team, including the physician. The staff contact person can assist in making any necessary arrangements.
3. Questions regarding any behavior support plan or behavior intervention plan, which correspond with the use of the medication, can be directed to the client's social worker, case manager, or psychologist.
4. I have the right to request a review at any time of my record, pursuant to § 51.30(4)(d) or § 51.30(5)(b).
5. I have a legal right to file a complaint if I feel that client rights have been inappropriately restricted. The client's social worker, case manager, or agency/facility client rights specialist may be contacted for assistance.
6. My consent permits the dose to be changed within the **anticipated dosage range** without signing another consent.
7. I understand the reasons for the use of the medication, its potential risks and benefits, other alternative treatment(s), and the probable consequences that may occur if the proposed medication is not given. I have been given adequate time to study the information and find the information to be specific, accurate, and complete.
8. This medication consent is for a period effective immediately and not to exceed fifteen (15) months from the date of my signature. The need for and continued use of this medication will be reviewed at least quarterly by the Interdisciplinary Team. The goal, on behalf of the client, will be to arrive at and maintain the client at the minimum effective dose.

SIGNATURES		**DATE SIGNED**
Client – If Presumed Competent to Consent/Parent of Minor/Guardian (POA-HC)	Relationship to Client ☐ Self ☐ Parent ☐ Guardian (POA-HC)	
Staff Present at Oral Discussion	Title	

Client / Parent of Minor / Guardian (POA-HC) Comments

As parent/guardian (POA-HC) was not available for signature, he/she was verbally informed of the information in this consent.

Verbal Consent

Obtained by – PRINT – Staff Name	Date Obtained	Written Consent Received ☐ Yes ☐ No
Obtained from – PRINT – Parent / Guardian (POA-HC) Name	Date Expires	Date Received

Client Initial _____ Date _____