

Consent for Use of Aripiprazole (Abilify) for Child/Youth in DCF Custody

District Office: _____

Social Worker: _____

Prescriber Name and Title: _____

<p>➤ I <input type="checkbox"/> do <input type="checkbox"/> do not consent to the administration of this medication protocol for this child for the next 180 days, beginning on _____ and ending on _____</p>
<p style="text-align: center;">_____</p> <p style="text-align: center;">Signature Date</p>

Directions

- A. Social Worker (SW) reads and/or completes his/her sections.
- B. SW sends form to Prescriber and schedules time for phone discussion.
- C. Prescriber fill in his/her sections.
- D. SW and Prescriber complete the following sections together during phone discussion (2c if necessary, 3 f-h; 4 e-f; 6a; 6b at follow-up).
- E. SW determines if DCF policy requires consultation or if SW feels the need for a consultation.
- F. After consulting with supervisor, SW decides whether authorize; signs, provides to prescriber, copy to child’s caregiver and child’s case file.

1. Child	<p>a. Name: DOB: Age:</p>
<p><i>(SW fills in a-d before sending to Prescriber.)</i></p>	<p>b. Height: Weight:</p>
	<p>c. Family medical history?</p> <p><input type="checkbox"/> diabetes <input type="checkbox"/> high blood pressure <input type="checkbox"/> high cholesterol <input type="checkbox"/> heart disease</p> <p><input type="checkbox"/> thyroid <input type="checkbox"/> other (specify)</p>
	<p>d. Medications currently on (include vitamins, herbal supplements):</p>
2. Medication	<p>a. Generic name: Aripiprazole</p>
<p><i>(SW reads a-e and discusses c with Prescriber if different.)</i></p>	<p>b. Product name: Abilify</p>
	<p>c. Suggested dose level:</p> <ul style="list-style-type: none"> <i>i. Initial dose: 2 mg/day</i> <i>ii. Recommended dose:</i> <ul style="list-style-type: none"> • 5 – 10 mg/day <i>iii. Literature based maximum dosage:</i> <ul style="list-style-type: none"> • Children: 15 mg/day • Adolescents: 30 mg/day <i>iv. FDA approved maximum dosage for children and adolescents:</i> <ul style="list-style-type: none"> • Approved for tx of Bipolar Mania or Mixed Episodes (age 10 – 17 years) and Schizophrenia (13 – 17 years): 30 mg/day • Approved for tx of irritability associated with Autistic Disorder (age

	<p>6 – 17 years): 15 mg/day v. <i>Schedule:</i> once daily</p>
	<p>d. <i>How does this medication work?</i> Cells in the brain communicate using chemicals called <i>neurotransmitters</i>. Too much or too little of these substances in parts of the brain can cause problems. Aripiprazole works in a different way than other atypicals, by changing the effects of two of these neurotransmitters—dopamine and serotonin—in certain areas of the brain.</p>
	<p>e. <i>Common reasons for prescribing this medication:</i> Aripiprazole is used to treat psychosis, such as in schizophrenia, mania, or very severe depression. It can reduce <i>positive symptoms</i> such as hallucinations (hearing voices or seeing things that are not there); delusions (troubling beliefs that other people do not share); agitation; and very unusual thinking, speech, and behavior. It is also used to lessen the <i>negative symptoms</i> of schizophrenia, such as lack of interest in doing things (apathy), lack of motivation, social withdrawal, and lack of energy. Aripiprazole may be used as a mood stabilizer in patients with bipolar disorder (manic-depressive illness) or severe mood swings. It can reduce mania and may be able to help maintain a stable mood over the long term. Sometimes aripiprazole is used to reduce severe aggression or very serious behavioral problems in young people with conduct disorder, mental retardation, autism, or pervasive developmental disorder. Aripiprazole may be used for behavior problems after a head injury. This medicine is very powerful and is used to treat very serious problems or symptoms that other medicines do not help.</p>
<p>3. Efficacy <i>(Prescriber fills out a-e and i.</i> <i>SW and Prescriber fill out f-h together.)</i></p>	<p>a. <i>Which symptoms of this child are the target for this prescription?</i></p> <p>b. <i>What do you expect it to do for this child?</i></p> <p>c. <i>How long does it typically take to see changes?</i> Be patient; the positive effects of this medicine may not appear for 2–3 weeks.</p> <p>d. <i>What is the probability of improvement with this child?</i></p> <p>e. <i>Is it important to use a specific brand of the medication for this child?</i></p> <p>f. <i>What psychosocial therapies do you recommend concurrently or sequentially to reduce target symptoms?</i></p>

	<p><i>g. Have these psychosocial therapies been tried with this child without this medication? For how long? Results? If not, why not?</i></p> <p><i>h. What other treatments are available to address the child's condition? How likely are they are to help?</i></p> <p><i>i. What is likely to happen if no treatment and/or no medication is provided?</i></p>
<p>4. Risks</p> <p><i>(SW reads a-d and schedules time to discuss e-f with Prescriber.</i></p> <p><i>SW informs Prescriber ASAP if client becomes pregnant.)</i></p>	<p><i>a. What serious side effects are possible?</i></p> <p>Stop the medicine and get <i>immediate</i> medical care:</p> <ul style="list-style-type: none"> • Trouble breathing or chest tightness • Swelling of lips, tongue, or throat • Stiffness of the tongue, jaw, neck, back, or legs • Seizure (fit, convulsion)—This is more common in people with a history of seizures or head injury. • Extreme stiffness or lack of movement, very high fever, mental confusion, irregular pulse rate, or eye pain—This is a medical emergency. Go to an emergency room right away. • Sudden stiffness and inability to breathe or swallow—Go to an emergency room or call 911. Tell the paramedics, nurses, and doctors that the patient is taking aripiprazole. Other medicines can be used to treat this problem quickly. <p>Tell the doctor in a day or two (if possible, before the next dose of medicine):</p> <ul style="list-style-type: none"> • Hives, itching, or rash—These could be signs of an allergic reaction. • Increased thirst, frequent urination (having to go to the bathroom often), lethargy, tiredness, dizziness, and blurred vision—These could be signs of diabetes (especially if your child is overweight or there is a family history of diabetes). <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>Black Box Warning: <i>Not approved for depression in under age 18. Increased the risk of suicidal thinking and behavior in short-term studies in children and adolescents with major depressive disorder and other psychiatric disorders.</i></p> </div> <p><i>b. What other, usually not serious, side effects are possible?</i></p> <p>Common:</p> <ol style="list-style-type: none"> 1. Daytime sleepiness or tiredness—Do not allow your child to drive, ride a bicycle or motorcycle, or operate machinery if this happens. This problem may be lessened by taking the medicine at bedtime. 2. Insomnia (trouble sleeping) 3. Headache

	<p>4. Nausea</p> <p>5. Vomiting</p> <p>6. Increased appetite</p> <p>7. Weight gain—Seek nutritional counseling; provide your child with low-calorie snacks and encourage regular exercise.</p> <p>Sometimes people who take aripiprazole gain weight, although this is less a problem with aripiprazole than with other atypicals. Children seem to have more problems with weight gain than adults. The weight gain may be from increased appetite and from ways that the medicine changes how the body processes food. Aripiprazole may also change the way that the body handles glucose (sugar) and cause high levels (hyperglycemia). People who take aripiprazole, especially those who gain a lot of weight, might be at increased risk of developing diabetes and of having increased fats (lipids—cholesterol and triglycerides) in their blood. Over time, both diabetes and increased fats in the blood may lead to heart disease, stroke, and other complications. The FDA has put warnings on all atypical agents about the increased risks of hyperglycemia, diabetes, and increased blood cholesterol and triglycerides when taking one of these medicines. It is much easier to prevent weight gain than to lose weight later. When your child first starts taking aripiprazole, it is a good idea to be sure that he or she eats a well-balanced diet without “junk food” and with healthy snacks like fruits and vegetables, not sweets or fried foods. He or she should drink water or skim milk, not pop, sodas, soft drinks, or sugary juices. Regular exercise is important for maintaining a healthy weight (and may also help with sleep).</p> <p>Rare:</p> <ol style="list-style-type: none"> 1. Dry mouth—Have your child try using sugar-free gum or candy. 2. Dizziness—This side effect is worse when the child stands up quickly, especially when getting out of bed in the morning; try having the child stand up slowly. 3. Increased restlessness or inability to sit still. 4. Shaking of hands and fingers. <p>One very rare side effect that may not go away is <i>tardive dyskinesia</i> (or TD). Patients with tardive dyskinesia have involuntary movements (movements that they cannot help making) of the body, especially the mouth and tongue. The patient may look as though he or she is making faces over and over again. Jerky movements of the arms, legs, or body may occur. There may be fine, wormlike or sudden repeated movements of the tongue, or the person may appear to be chewing something or smacking or puckering his or her lips. The fingers may look as though they are rolling something. If you notice any unusual movements, be sure to tell the doctor. The doctor may use the AIMS test to look for these movements.</p> <ol style="list-style-type: none"> 5. Decreased or slowed movement and decreased facial expressions. 				
	<p>c. <i>Is there any way to minimize the chances of experiencing these side effects?</i></p> <p>These side effects often can be helped by:</p> <ul style="list-style-type: none"> • lowering the dose of medicine, • changing the times medicine is taken, or • adding another medicine. <p>The following medicines may be used to treat the movement side effects of aripiprazole. These medicines may have their own side effects as well. Ask the doctor if you suspect a problem.</p> <table border="0"> <tr> <td style="text-align: center;"><u>Brand name</u></td> <td style="text-align: center;"><u>Generic name</u></td> </tr> <tr> <td style="text-align: center;">Akineton</td> <td style="text-align: center;">biperiden</td> </tr> </table>	<u>Brand name</u>	<u>Generic name</u>	Akineton	biperiden
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	<p>Artane trihexyphenidyl Ativan lorazepam* Benadryl diphenhydramine* Catapres clonidine* Cogentin benztropine mesylate* Inderal propranolol* Klonopin clonazepam* Symmetrel amantadine</p> <p>*Medicine has its own information sheet in the Dulcan book.</p>
	<p><i>d. Does this medication cause any reactions when taken with other medications?</i></p> <p>Please note that the following are only the most likely interactions with food or other medicines.</p> <ul style="list-style-type: none"> • Aripiprazole can be taken with or without food. • Taking aripiprazole together with Prozac (fluoxetine), Tagamet (cimetidine), or Paxil (paroxetine) can increase levels of aripiprazole and increase the risk of side effects. • Taking aripiprazole together with carbamazepine (Tegretol) can decrease the levels of aripiprazole so that it does not work as well. • It is better to limit drinks with caffeine (coffee, tea, soft drinks) because caffeine works in the opposite way from this medicine, and the positive effects might be decreased.
	<p><i>e. What are the risks if the youth uses alcohol or other substances?</i></p> <p>Alcohol should be avoided while taking aripiprazole.</p>
	<p><i>f. What are the risks if the young woman becomes pregnant?</i></p> <p>It is not known whether aripiprazole can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. Aripiprazole should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.</p>
<p>5. Instructions</p> <p><i>(SW reads a-d and schedules time to discuss e on phone with Prescriber.)</i></p>	<p><i>a. How is this medication taken?</i></p> <p><input type="checkbox"/> tablets <input type="checkbox"/> orally disintegrating tablets <input type="checkbox"/> oral solution</p> <p><i>b. Are there any food or lifestyle suggestions or restrictions?</i></p> <p>Taking this medicine could make overheating or heatstroke more likely. Have the child decrease activity in hot weather, stay out of the sun, and drink plenty of water to prevent this.</p> <p><i>c. If a dose is late or missed, what should be done?</i></p> <p>Take the missed dose as soon as it is noticed. If it is almost time for the next dose, just skip the missed dose and take the next dose at the regular time. Do not take two doses at the same time.</p> <p><i>d. What could happen if this medication is stopped suddenly?</i></p>

	<ol style="list-style-type: none"> 1. Involuntary movements, or withdrawal dyskinesias, may appear within 1–4 weeks of lowering the dose or stopping the medicine. Usually these go away, but they can last for days to months. 2. If aripiprazole is stopped suddenly, emotional disturbance (such as irritability, nervousness, moodiness, or oppositional behavior) or physical problems (such as stomachache, loss of appetite, nausea, vomiting, diarrhea, sweating, indigestion, trouble sleeping, trembling, or shaking) may appear. These problems usually last only a few days to a few weeks. If they happen, you should tell your child’s doctor. The medicine dose may need to be lowered more slowly (tapered). Always check with the doctor before stopping a medicine.
	<p>e. What needs to occur for you to consider starting a process to taper off?</p>
<p>6. Monitoring</p> <p><i>(SW discusses with Prescriber at 6-month follow-up.)</i></p>	<p>a. How will the use of the medication be monitored with this child?</p> <p>Be sure to tell the doctor if anyone in the family has diabetes, high blood pressure, high cholesterol, or heart disease.</p> <p>Policy recommendations are:</p> <ol style="list-style-type: none"> i. personal and family history at baseline and annually ii. waist circumference at baseline and annually iii. weight and BMI at baseline, every 4 weeks up to 12 weeks, and then quarterly iv. blood pressure at baseline, twelve weeks, and then annually v. fasting plasma glucose at baseline, 12 weeks, and annually vi. fasting lipid profile at baseline, 12 weeks, and annually
	<p>b. At follow-up:</p> <ol style="list-style-type: none"> i. When were these tests done? ii. Any undesirable or abnormal results?

Information adapted from: Dulcan MK (editor): *Helping Parents, Youth, and Teachers Understand Medications for Behavioral and Emotional Problems: A Resource Book of Medication Information Handouts*, Third Edition. Washington, DC, American Psychiatric Publishing, 2007.