INFORMED CONSENT FOR MEDICATION

Dosage and / or Side Effect information last revised on 08/09/2018

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
Atypical Antipsychotic	Aristada (aripiprazole lauroxil)	• Prior to initiating treatment with the extended-release IM formulation, establish tolerability with oral aripiprazole, which may take up to 2 weeks. • Initial, 441 mg IM (deltoid or gluteal) once monthly OR 662 mg IM (gluteal only) once monthly OR 882 mg IM (gluteal only) once monthly or every 6 weeks. Individualize based on established tolerability to oral dosing: if on 10 mg/day orally, give 441 mg IM/month; 15 mg/day orally, give 662 mg IM/month; 20 mg/day or greater orally, give 882 mg IM/month. Administer with oral aripiprazole for 21 days in conjunction with the initial IM injection.	

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

Client Initial _____ Date _____

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

- Dermatologic: Injection site pain (3% to 4%), Injection site reaction (4% to 5%).
- Endocrine metabolic: Weight increased (2% to 10%).
- Neurologic: Akathisia (11%), Extrapyramidal sign (5% to 7%), Headache (3% to 5%), Insomnia (3% to 4%).

Less Common Side Effects

- Cardiovascular: Orthostatic hypotension (0.2% to 0.5%).
- Endocrine metabolic: Decreased HDL level (15%), High hemoglobin A1c level (14%), Hyperglycemia, Raised low density lipoprotein cholesterol (1% to 8%), Serum cholesterol raised (1% to 15%), Serum triglycerides raised (8% to 35%).
- Hematologic: Agranulocytosis, Leukopenia, Neutropenia.
- Neurologic: Cerebrovascular accident, impaired cognition, Impaired psychomotor performance, Seizure, Tardive dyskinesia, Transient ischemic attack.
- Psychiatric: Suicidal behavior.
- Other: Increased body temperature, Neuroleptic malignant syndrome.

Caution

- Body temperature regulation: Disruption in ability to reduce core body temperature has been reported with antipsychotic agents, especially following strenuous exercise, exposure to extreme heat, concomitant anticholinergic medication, or dehydration.
- Cardiovascular: Orthostatic hypotension has been reported; increased risk in patients with preexisting cardiovascular or cerebrovascular disease, dehydration, hypovolemia, and concomitant use of antihypertensives or in patients who are naive to antipsychotic.
- Dosage and duration: Higher cumulative dose and longer treatment duration increase risk of potentially irreversible tardive dyskinesia.
- Endocrine and metabolic: Patients with preexisting or risk factors for diabetes mellitus, including obesity and family history of diabetes, may experience hyperglycemia or worsening of glucose control; monitoring recommended.
- Endocrine and metabolic: Severe hyperglycemia, sometimes in association with ketoacidosis, hyperosmolar coma, or death, has been reported with atypical antipsychotics.
- Endocrine and metabolic: Dyslipidemia has been reported with atypical antipsychotics.
- Endocrine and metabolic: Weight gain has been reported with atypical antipsychotics; monitoring recommended.
- Gastrointestinal: Dysphagia has been reported with antipsychotic agents and may result in aspiration pneumonia due to esophageal dysmotility.
- Hematologic: Agranulocytosis, leukopenia, and neutropenia have been reported with atypical antipsychotics; risk factors may include history of a low WBC or absolute neutrophil count, leukopenia, or neutropenia; monitoring recommended and discontinuation may be necessary.
- Immunologic: Hypersensitivity reactions have been reported with severity ranging from pruritus or urticaria to anaphylaxis.
- Musculoskeletal: Tardive dyskinesia has been reported and may be irreversible; discontinuation may be required.
- Neuroleptic malignant syndrome: Has been reported; may require discontinuation of therapy and medical management; reinitiate therapy with monitoring.
- Neurologic: Cerebrovascular adverse events, including fatal stroke, have occurred in elderly patients with dementia (unapproved use).
- Neurologic: Seizures; increased risk with a history of seizures and conditions that lower seizure threshold
- Neurologic: Cognitive and motor impairment is possible; driving or operating machinery not recommended until effects are realized.
- Psychiatric: Compulsive behaviors and impaired impulse control (e.g., urges to gamble, binge eat, shop, increased sexual urges, other intense urges) have been reported; monitoring recommended and dose reduction or discontinuation may be necessary.
- Special populations: Elderly patients are at increased risk of potentially irreversible tardive dyskinesia, especially elderly women.
- **Falls: possibility that you may experience somnolence, postural hypotension, or motor and sensory instability, which may lead to the risk of falls, particularly in patients with diseases, conditions, or medications that could exacerbate these effects.**
- **Pregnancy: may cause extrapyramidal and/or withdrawal symptoms in a neonate and to notify their healthcare provider with a known or suspected pregnancy. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ARISTADA during pregnancy.**

BLACK BOX WARNING

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Aripiprazole lauroxil is not approved for the treatment of patients with dementia-related psychosis.

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

Client Initial _____ Date _____

Medication: Aristada – (Aripiprazole Lauroxil)

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 _____