DEPARTMENT OF HEALTH SERVICES
Division of Mental Health and Substance Abuse 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 05/09/2016

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	Invega Trinza (paliperidone palmitate)	• Invega Trinza(TM), 3-month extended-release injection) Initial, after 4 doses of monthly injections with Invega(R) Sustenna(R) (last 2 doses of same strength), give Invega Trinza(TM) 273 mg IM if previous monthly dose was 78 mg IM; 410 mg IM if previous monthly dose was 117 mg IM; 546 mg IM if previous monthly dose was 156 mg IM; 819 mg IM if previous monthly dose was 234 mg IM. May give up to 7 days before or after the next scheduled 1-month dose [1]. • (Invega Trinza(TM), 3-month extended-release injection) Maintenance, give IM once every 3 months; may increase dose in 3-month increments within the range of 273 to 819 mg; full effects of any dose adjustment may not be evident for several months.	

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:

Client Initial _____ Date _____

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.

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 reaction (Up to 12%).

- Endocrine metabolic: Hyperprolactinemia (32% to 46%), Weight gain (5.8% to 18.4%).
- Neurologic: Akathisia (1% to 11%), Dizziness (1% to 6%), Extrapyramidal disease (Up to 12%), Headache (6% to 15%), Parkinsonism (4% to 18%).
- Psychiatric: Agitation (4% to 10%**).**

Less Common Side Effects

Cardiovascular: Orthostatic hypotension (Less than 1%), Prolonged QT interval, Syncope (Less than 1%).

- Hematologic: Agranulocytosis, Leukopenia, Neutropenia.
- Immunologic: Anaphylaxis (Rare).
- Neurologic: Grand mal seizure (Less than 1%), Seizure (Less than 1%), Tardive dyskinesia.
- Reproductive: Priapism.
- Other: At risk for imbalanced body temperature, Neuroleptic malignant syndrome.

Caution

- Cardiovascular: QT-interval prolongation has been reported; avoid use in patients with a history of cardiac arrhythmias or congenital long QT syndrome due to increased risk of QT interval prolongation, torsade de pointes, or sudden death.
- Cardiovascular: Orthostatic hypotension and syncope have been reported; use cautiously in patients with cardiovascular or cerebrovascular disease or conditions with risk of hypotension (e.g., dehydration, hypovolemia, concomitant antihypertensive medications); monitoring is recommended.
- Concomitant use: Avoid use with other QT-prolonging drugs due to increased risk of torsade de pointes or sudden death.
- Elderly patients: Increased risk of tardive dyskinesia, especially elderly women.
- Endocrine and metabolic: Hyperglycemia (some cases extreme and associated with ketoacidosis, hyperosmolar coma, or death) has been reported with atypical antipsychotic use; monitoring is recommended.
- Endocrine and metabolic: Patients with diabetes mellitus or risk factors for diabetes mellitus (e.g., obesity, family history) have increased risk of worsening of glucose control or severe hyperglycemia; monitoring is recommended.
- Endocrine and metabolic: Weight gain may occur with atypical antipsychotic use; monitoring is recommended.
- Endocrine and metabolic: Dyslipidemia has been reported.
- Endocrine and metabolic: Hyperprolactinemia may occur; chronic administration may lead to hypogonadism and decreases in bone density.
- Endocrine and metabolic: Use cautiously among patients with conditions that may contribute to elevated body temperature (e.g., strenuous exercise, extreme heat exposure, dehydration, concomitant anticholinergic use), as disruption of body temperature regulation has been reported with use of antipsychotic agents.
- Gastrointestinal: Esophageal dysmotility and aspiration may occur; use cautiously in patients at risk for aspiration pneumonia.
- Hematologic: Myelosuppression (ie, agranulocytosis, leukopenia, neutropenia) has been reported, with increased risk among patients with low WBC or history of drug-induced leukopenia or neutropenia; monitoring is recommended and discontinue with significant WBC declines with no other causative factors or with severe neutropenia (i.e., absolute neutrophil count less than 1000/mm[3]).
- Immunologic: Anaphylaxis, angioedema, and other hypersensitivity reactions have been reported.
- Neurologic: Potentially fatal neuroleptic malignant syndrome (NMS) has been reported with use of antipsychotic drugs; immediately discontinue if NMS is suspected, and close monitoring recommended if therapy reintroduced after resolution.
- Neurologic: Potentially irreversible tardive dyskinesia may occur, with increased risk associated with extended treatment duration and higher cumulative doses; discontinuation may be necessary.
- Neurologic: Seizures have been reported; use cautiously in patients with seizure history or conditions that lower the seizure threshold.
- Neurologic: Patients with Parkinson disease or dementia with Lewy bodies may experience increased sensitivity to antipsychotic medications.
- Reproductive: Priapism has been reported with oral paliperidone administration.

Warning

Black box warning: Increased risk of death and cerebrovascular events (i.e., stroke, TIA) among elderly patients with dementia-related psychosis.

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 _____