**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

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 agent | Latuda® (lurasidone) | 20 mg to 160 mg once daily | |

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.

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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** dyslipidemia, nausea, vomiting, akathisia, extrapyramidal disease, insomnia, parkinsonism, somnolence

**Less Common Side Effects** orthostatic hypotension, tachycardia, hyperprolactinemia, increased appetite, weight increased, diarrhea, excessive salivation, indigestion, xerostomia, viral disease, backache, dizziness, dystonia, agitation, anxiety, restlessness, serum creatinine above reference range, urinary tract infection, nasopharyngitis, rhinitis, influenza

**Rare Side Effects** syncope, cerebrovascular accident, seizure, hypomania

**Caution**

Precaution:

Access: While coadministration between medication-assisted treatment drugs (MAT; eg, methadone and buprenorphine) and benzodiazepines or other CNS depressants (including alcohol) may increase the possibility of harm, including overdose and death, concomitant therapy with MAT may be appropriate in some patients; if concomitant use is necessary, careful management and monitoring recommended.

Cardiovascular: Orthostatic hypotension and syncope may occur, especially upon treatment initiation and when increasing doses. Patients at an increased risk of development include those with dehydration, hypovolemia, concurrent antihypertensive medication use, cardiovascular disease or cerebrovascular disease, and patients who are initiating antipsychotic therapy for the first time. Monitoring is recommended and dose adjustment may be necessary.

Concomitant use: Coadministration of central nervous system depressants, including antipsychotics, with opioids may result in profound sedation, respiratory depression, coma, or death. The addition of a nonsedating antipsychotic, including lurasidone, to prescription opioids was associated with significantly higher risk of unintentional overdose within 30 days compared with opioids alone.

Endocrine and metabolic: Body temperature regulation may be disrupted with antipsychotic use. Use caution if core body temperature is elevated (eg strenuous exercise, extreme heat exposure, concomitant use of anticholinergic medications, or dehydration). Patients with diabetes mellitus or risk factors for diabetes mellitus (eg obesity, family history of diabetes) have an increased risk of severe, potentially fatal, hyperglycemia. Monitoring is recommended. Dyslipidemia has been reported with atypical antipsychotic use. Cardiovascular and cerebrovascular risk may be increased. Monitoring is recommended. Hyperglycemia, including severe cases associated with ketoacidosis, hyperosmolar coma, or death, has been reported with atypical antipsychotic use. Monitoring is recommended. Hyperprolactinemia has been reported. Weight gain may occur with antipsychotic use. Weight gain may increase cardiovascular and cerebrovascular risk. Monitoring is recommended.

Falls: Falls that may lead to fracture or other injuries may occur as a result of somnolence, postural hypotension, or motor or sensory instability. Assessment of risk of a fall recommended.

Gastrointestinal: Esophageal dysmotility and aspiration may occur. This may lead to potentially fatal aspiration pneumonia, especially in elderly patients and those with severe Alzheimer's dementia. Use with caution in patients at risk for aspiration pneumonia.

Hematologic: Leukopenia and neutropenia, including agranulocytosis (some cases fatal), have been reported with antipsychotic drugs, especially in patients with a baseline low white blood cell count or history of leukopenia or neutropenia. Monitoring is recommended especially during the initial months of therapy. If neutropenia develops, monitor for signs and symptoms of infection. Discontinuation may be required.

Neurologic: Cerebrovascular adverse events (stroke and TIA), including fatalities, have been reported in association with antipsychotic agents in elderly patients with dementia (unapproved use). Cognitive and motor impairment may occur. Use caution when operating machinery or vehicles. Patients with dementia with Lewy bodies may have increased sensitivity to antipsychotics, which may result in confusion, frequent falls and clinical features consistent with neuroleptic malignant syndrome. Neuroleptic malignant syndrome, potentially fatal, has been reported. Immediately discontinue use if suspected. Patients with Parkinson's disease may have an increased sensitivity to antipsychotics, which may result in confusion, frequent falls and clinical features consistent with neuroleptic malignant syndrome. Patients with a history of seizure or conditions that lower the seizure threshold (eg Alzheimer dementia) may have increased risk of seizures. Patients 65 years of age and older may have a higher risk of conditions that lower the seizure threshold. Tardive dyskinesia, potentially irreversible, may occur with antipsychotic treatment. Prevalence may be higher in elderly patients, especially women. Risk may increase with prolonged duration of treatment and higher total cumulative dose. Discontinuation may be considered.

Psychiatric: Mania or hypomania may occur, especially in patients with bipolar disorder. Monitoring is recommended.

Special populations (Beers Criteria): Avoid use due to an increased risk of cerebrovascular accident. Exceptions are use for schizophrenia, bipolar disorder, adjunctive treatment of major depressive disorder, or short-term use as antiemetic during chemotherapy. Avoid use for



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behavioral problems of dementia or delirium in elderly as antipsychotics may increase the rate of cognitive decline and mortality (unless nonpharmacological measures fail and the patient is a threat to self or others). If use is required consider periodic discontinuation to assess need and/or lowest effective dose. Avoid use in elderly patients with Parkinson's Disease as symptoms may worsen and in patients with a history of falls or fractures (unless safer alternatives are not available) due to risk for ataxia, impaired psychomotor performance, syncope or additional falls. If used, caution is advised and monitoring is recommended as SIADH or hyponatremia may occur or be exacerbated. Avoid concomitant use of 3 or more CNS-active agents in any combination due to increased risk of fall.

**Warning**

Black Box 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 of death. Lurasidone is not approved for the treatment of patients with dementia-related psychosis.
Suicidal Thoughts and Behaviors:
Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors. Lurasidone is not approved for use in pediatric patients with depression.

**Syndrome Note**

Neuroleptic malignant syndrome:
Neuroleptic malignant syndrome (NMS), a potentially fatal symptom complex, has been reported with the use of antipsychotic drugs including lurasidone hydrochloride. It typically presents as hyperpyrexia, muscle rigidity, autonomic instability, altered mental status, evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia), elevated CPK levels, myoglobinuria, and acute renal failure. Immediately discontinue use and intensive symptomatic treatment and monitoring would be needed if suspected.

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



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Medication: Latuda® – (lurasidone)

**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 _____