**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 06/01/2020**

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 |
|---|---|---|---|
| Atypical Antipsychotic/Mood | VRAYLAR (cariprazine) | 1.5 mg to 6 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**:

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**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



**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:** indigestion; nausea; vomiting; constipation; diarrhea; headache; akathisia (feeling that you cannot sit still/ need to move); extrapyramidal movements (spasms, muscle contractions/ rigidity, jerk-like movements, shuffling of the feet, or abnormally slowed movements); somnolence; restlessness; weight gain; excessive sweating.

**Less Common Side Effects:** hypertension (high blood pressure); tachycardia (rapid heartbeat); toothache; decreased appetite; fatigue; muscle rigidity; back, limb, or joint pain; changes in vision or blurred vision; orthostatic hypotension (dizziness when standing up from a lying or sitting position); diabetes mellitus; dyslipidemia; hyperglycemia (high blood sugar)**.**

**Rare Side Effects:** Although rare, check with you doctor as soon as possible if any of the following occur: new or worsening thoughts of suicide; impaired judgment; pulmonary aspiration (entry of fluid or food into the lungs); impaired body temperature regulation: neuroleptic malignant syndrome (NMS): a rare and serious condition that can lead to death. Symptoms of NMS include high fever, stiff muscles, confusion, sweating, changes in pulse, heart rate, and/or an abnormally high or low blood pressure; leukopenia (low white blood cell count); neutropenia (low neutrophil count; a type of white blood cell); fatal agranulocytosis (severely low white blood cells); tardive dyskinesia: Abnormal movements that you cannot control in your face, tongue or other body parts. Tardive dyskinesia may not go away, even if you stop taking VRAYLAR, and may start after you stop taking the medication.; seizures; stevens-johnson syndrome (rash); acid reflux; cerebrovascular accident (stroke).

**Caution**

- **Orthostatic hypotension (dizziness when standing)**
  This medication may cause dizziness when standing from a lying or seated position. Take caution by standing up slowly. Fainting may occur, especially during initial dose titration, dosage increases, and in patients with known cardiovascular disease (e.g., history of myocardial infarction, ischemic heart disease, heart failure, or conduction abnormalities), cerebrovascular disease, or at risk for hypotension (e.g., elderly, dehydration, hypovolemia, and antihypertensive therapy); monitoring recommended for at risk patients.
- **Hyperglycemia (high blood sugar)**
  Some cases can be extreme and is associated with ketoacidosis, hyperosmolar coma, or death. Close monitoring of blood sugar levels, especially for people with diabetes, is recommended.
- **Temperature regulation**
  Disruption of body temperature regulation has been reported with atypical antipsychotic use; caution advised in patients with conditions that may contribute to elevated body temperature (e.g., strenuous exercise, extreme heat exposure, dehydration, concomitant anticholinergic use).
- **Hypersensitivity reactions**
  These reactions have been reported, including rash, pruritus, urticaria (hives), and events suggestive of angioedema (e.g., swollen tongue, lip, or face).
- **Neuroleptic malignant syndrome**
  Has been reported in association with antipsychotics and may be life-threatening; Symptoms of NMS include high fever, stiff muscles, confusion, sweating, changes in pulse, heart rate, and/or an abnormally high or low blood pressure; discontinue immediately if suspected and monitor closely.
- **Tardive Dyskinesia**
  Abnormal movements that you cannot control in your face, tongue or other body parts. Tardive dyskinesia may not go away, even if you stop taking VRAYLAR, and may start after you stop taking the medication. This may occur, with increased risk among elderly, especially elderly women, and patients treated with higher cumulative doses or longer treatment duration; discontinuation may be required.
- **Seizures**
  Although rare, this may occur; use caution in patients with a history of seizures, the elderly, or with conditions that lower seizure threshold.
- **Driving and operating heavy machinery**
  Potential cognitive and motor impairment may affect how patients operate machinery or motor vehicles; caution advised until drug effects are known.
- **Respiratory aspiration (fluid or food accumulation in the lungs)**
  This may occur in at-risk patients, as esophageal dysmotility and aspiration have been reported with antipsychotic drug use.



Client Initial _____ Date _____

**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. VRAYLAR (cariprazine) is not approved for the treatment of 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 _____