DEPARTMENT OF HEALTH SERVICES
Division of Care and Treatment Services
F-24277 (09/2016)

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 02/24/2017

Completion of this form is voluntary. If not completed, 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/day	

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 "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

- Gastrointestinal: Indigestion (4% to 7%), Vomiting (4% to 10%).
- Neurologic: Akathisia (Schizophrenia, 9%; bipolar, 20%), Extrapyramidal sign (Schizophrenia, 15%; bipolar, 26%), Somnolence (5% to 8%).
- Psychiatric: Restlessness (4% to 7%).

Less Common Side Effects

- Cardiovascular: Ischemic stroke (Up to 0.1%), Orthostatic hypotension.
- Endocrine metabolic: Diabetes mellitus, Dyslipidemia, Hyperglycemia.
- Gastrointestinal: Esophageal dysmotility.
- Hematologic: Leukopenia, Neutropenia.
- Musculoskeletal: Tardive dyskinesia.
- Neurologic: Seizure.
- Psychiatric: At risk for suicide (Up to 1%), Loss of judgment.
- Respiratory: Pulmonary aspiration.
- Other: Body temperature finding, Body temperature dysregulation, Neuroleptic malignant syndrome.

Caution

- Cardiovascular: Orthostatic hypotension and syncope 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.
- Endocrine and metabolic: Hyperglycemia (some cases extreme and associated with ketoacidosis, hyperosmolar coma, or death) has been reported with atypical antipsychotic use; monitoring recommended.
- Endocrine and metabolic: Metabolic changes (i.e., dyslipidemia, body weight gain, and hyperglycemia) have been reported with atypical antipsychotic use; monitoring recommended.
- Endocrine and metabolic: 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).
- Gastrointestinal: Dysphagia has been reported, and esophageal dysmotility and aspiration have been reported with antipsychotic use; caution advised in patients at risk for aspiration.
- Hematologic: Fatal agranulocytosis has been reported with antipsychotic use.
- Hematologic: Leukopenia and neutropenia have been reported, with increased risk among patients with a history of drug-induced leukopenia or neutropenia, low WBC, or low absolute neutrophil count (ANC); monitoring recommended and discontinuation may be required.
- Immunologic: Hypersensitivity reactions have been reported, including rash, pruritus, urticaria, and events suggestive of angioedema (e.g., swollen tongue, lip swelling, face edema, pharyngeal edema, and swelling face).
- Late-occurring adverse reactions: Adverse events may not appear for several weeks after initiation due to accumulation of cariprazine and its metabolites; monitoring recommended for several weeks after starting therapy or dosage increases and discontinuation may be required.
- Neuroleptic malignant syndrome: Has been reported in association with antipsychotics and may be life-threatening; discontinue immediately if suspected and monitor closely.
- Neurologic: Cerebrovascular adverse reactions including stroke, fatal stroke, and transient ischemic attack occurred more frequently in elderly patients with dementia-related psychosis (unapproved use) after antipsychotic therapy.
- Neurologic: Potentially irreversible tardive dyskinesia 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.
- Neurologic: Seizures may occur; use caution in patients with a history of seizures, the elderly, or with conditions that lower seizure threshold.
- Neurologic: Potential cognitive and motor impairment may affect how patients operate machinery or motor vehicles; caution advised until drug effects are known.
- Respiratory: Aspiration may occur in at-risk patients, as esophageal dysmotility and aspiration have been reported with antipsychotic drug use.

Warning

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 PDR for an all-inclusive list of side effects.

Medication: VRAYLAR – (cariprazine)

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 _____