DSH PSYCHOTROPIC MEDICATION Operational Procedures

CARIPRAZINE PROTOCOL:

I. Indications:

A. At least one of the following clinical indications is present and documented in the chart:

1. DSM diagnosis of schizophrenia, schizoaffective disorder or other psychotic disorder (e.g., major depression with psychotic features). Also, may adjunctively assist in depression treatment.

2. DSM diagnosis of bipolar I disorder for acute treatment during a current episode, manic or mixed (if used beyond three weeks, long-term usefulness is reevaluated).

3. Severe persistent aggression or self-injurious behavior with evidence that a behavioral treatment, as part of a formal treatment program, was adequately implemented and found to be ineffective.

B. Contraindications:

Hypersensitivity to cariprazine or any component of its formulation.

II. Precautions (risk/benefit analysis supports use):

A. Signs or history of extrapyramidal symptom (EPS) sensitivity, especially akathisia, or tardive dyskinesia.

B. Pregnancy or breast feeding. May cause neonatal dyskinesia.

C. Elderly patient with neurocognitive disorder-related psychosis (not FDA approved for such patients).

D. History of leukopenia or severe neutropenia. The risk is low for cariprazine; however, the U.S. Food and Drug Administration has mandated a class warning for the second/third-generation antipsychotics.

III. The following initial workup should be completed:

A. There is informed consent or alternate legal authorization.

B. There is chart documentation of:

1. Waist circumference.

2. Personal or family history of diabetes.

3. Personal history of high BMI (>25).

4. Personal history of elevated triglycerides or hypercholesterolemia.

C. Initial workup includes:

1. Fasting blood glucose and/or Hgb A1c (optional) within 30 days.

2. Lipid panel or total cholesterol and triglycerides within 30 days.

3. AIMS rating within one year.

4. ECG within one year.

IV. Monitoring:

A. Monthly monitoring includes weight/BMI.

B. Semi-annual monitoring includes:

1. Fasting serum glucose and/or Hgb A1c (optional).

2. Lipid panel and/or triglycerides and cholesterol.

C. Annual monitoring includes waist circumference, ECG, and AIMS.

D. Positive AIMS results in quarterly monitoring, until negative twice.

E. Fasting serum glucose levels of 100 mg/dL or higher or elevated Hgb A1c result in glucose tolerance test or 2-hour postprandial blood glucose measurement and medical consultation.

F. Nutritional consultation and appropriate dietary and exercise interventions are pursued if any of the following weight gain indicators occurs:

1. Weight % increase of 5% in one month, 7.5% in three months or 10% in six months.

2. Waist circumference increase from below 35in. to > 35in. for females and from below 40in. to > 40in. for males.

3. BMI increase from normal to overweight (from <25 to >25) or from overweight to obese (from 25 – 29.9 to 30 or higher).

G. Abnormal or rising triglyceride and cholesterol levels result in medical consultation and appropriate interventions.

V. Dose initiation and titration:

A. Typical initial dose is 1.5 – 3 mg daily, with titration as tolerated to up to 6 mg per day. Rapid titration is more likely to result in nausea/vomiting or neurological

adverse effects. The average half-life is 2 to 5 days, meaning it may require 10 to 25 days to reach steady-state. Doses greater than 6 mg per day continued for more than 15 days require Medication Review Committee (MRC) or Therapeutic Review Committee (TRC) consultation or review.

In general, oral antipsychotics should be titrated upward every two weeks until one of four endpoints is reached, i.e., the desired clinical result is achieved, intolerable unmanageable adverse effects are encountered, the point of futility for the antipsychotic is reached, or an upper dose limit established by law or regulation is reached.

B. Dose accounts for drug-drug interactions:

1. Use with CYP 3A inducers (e.g., carbamazepine, phenytoin, phenobarbital, primidone, oxcarbazepine or some glucocorticoids is not recommended.)

2. CYP 3A inhibitors: Use with potent CYP 3A inhibitors (e.g., clarithromycin, telithromycin, nefazodone, itraconazole, ketoconazole, atazanavir, darunavir, indinavir, lopinavir, nelfinavir, ritonavir, saquinavir, and tipranavir) may require dose reductions of circa 50%.

VI. Possible Adverse Reactions:

A. Headache.

B. Anxiety.

C. Insomnia.

D. Agitation.

E. Esophageal dysmotility.

F. Dyspepsia.

G. Nausea.

H. Vomiting.

I. Anorexia.

J. Constipation.

K. Light headedness.

L. Dizziness.

M. Seizures (one of lowest risks among antipsychotics).

N. Blurred vision.

O. Somnolence (one of lowest risks among antipsychotics).

P. Akathisia.

Q. Extrapyramidal signs.

R. Tardive dyskinesia.

S. Neuroleptic malignant syndrome.

T. Orthostatic hypotension (one of lowest risks among antipsychotics).

U. Weight gain or loss.

V. Hyperglycemia and diabetes mellitus.

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