Clinical Policy: Cariprazine (Vraylar®)

Reference Number: PMA_10-11-22
Effective Date: New

Medication class: 2nd Generation Antipsychotic

Indications for use: Vraylar® is FDA approved for the treatment of:
- Schizophrenia
- Acute manic or mixed episodes associated with Bipolar I disorder

Description
The intent of the criteria is to ensure that members follow selection elements established by Cenpatico Integrated Care (Cenpatico IC) medical policy for cariprazine (Vraylar®)

Policy/Criteria
It is the policy of Cenpatico IV that cariprazine (Vraylar®) is medically necessary for members meeting the following criteria:

Initial Approval Criteria (must meet all):

I. Schizophrenia (must meet all)
   A. Diagnosis of schizophrenia;
   B. Age ≥ 18 years;
   C. Trial and failure of THREE of the following atypical antipsychotics: ziprasidone, olanzapine, quetiapine, Fanapt, Saphris, Latuda; each agent must be trialed for ≥ 4 weeks at therapeutic doses for schizophrenia, unless contraindicated;
   D. Trial and failure of ≥ 4 weeks of aripiprazole at a therapeutic dose for schizophrenia, unless contraindicated;
   E. Request does not exceed 6 mg/day.

Approval duration: 12 months

II. Acute manic or mixed episodes associate with Bipolar 1 disorder (must meet all criteria A-E)
   A. Diagnosis of Bipolar I disorder acute manic/mixed episodes;
   B. Age ≥ 18 years;
   C. Trial and failure of THREE of the following atypical antipsychotics: ziprasidone, olanzapine, quetiapine, Saphris; each agent must be trialed for ≥ 4 weeks at therapeutic doses for Bipolar I disorder, unless contraindicated;
   D. Failure of ≥ 2 weeks of aripiprazole at a therapeutic dose for schizophrenia, unless contraindicated;
   E. Request does not exceed 6 mg/day.

Approval duration: 12 months
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III. New patient stable on Vraylar (must meet all)
   A. Member has a diagnosis of schizophrenia or
   B. Member has used Vraylar for at least 30 days
   C. Request does not exceed 6 mg/day.

   Approval duration: 12 months

Continued Approval (must meet all as applicable):

   A. If request is for a dose increase, there must be evidence of compliance to current regimen;
   B. Dose must not exceed 6 mg/day.

   Approval duration: 12 months

Background
Vraylar (cariprazine) is an orally administered capsule indicated for the treatment of schizophrenia and the acute treatment of manic or mixed episodes associated with bipolar I disorder. Although the mechanism of action is unknown, cariprazine’s efficacy could be mediated through a combination of partial agonist activity at central dopamine D2 and serotonin 5-HT1A receptors and antagonist activity at serotonin 5-HT2A receptors. Common adverse effects include extrapyramidal symptoms, akathesia, dyspepsia, vomiting, somnolence and restlessness.

Available dosage forms:
Vraylar Capsules: 1.5 mg, 3 mg, 4.5 mg, 6 mg

Usual dose:
Vraylar®: Schizophrenia – starting dose 1.5 mg/day  Maximum daily dose: 6 mg/day
Bipolar I disorder,
manic/mixed – starting 1.5 mg/day  Maximum daily dose: 6 mg/day

References (or Bibliography)
1. Vraylar Drug Monograph

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