

Antipsychotics – 2nd Generation: Vraylar

Medical policy no. 59.40.00.18

Effective Date: TBD

Note: New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.

Background:

Cariprazine (Vraylar) is an atypical antipsychotic and is indicated for the treatment of acute manic or mixed episodes associated with bipolar I disorder, depressive episodes associated with bipolar I disorder, and schizophrenia in adults. Cariprazine works as a partial agonist of serotonin 5-HT-1a and dopamine D2 receptors and as an antagonist of serotonin 5-HT-2A.

Medical necessity

Drug	Medical Necessity
cariprazine (Vraylar)	Cariprazine may be considered medically necessary when prescribed for the treatment of: <ul style="list-style-type: none"> • Bipolar I Disorder, acute mixed or manic episodes • Depressed bipolar I disorder • Schizophrenia

Clinical policy:

Clinical Criteria	
Bipolar I Disorder, acute mixed or manic episodes	Cariprazine may be covered when ALL of the following are met: <ol style="list-style-type: none"> 1. Client is 18 years of age or older 2. Client meets ONE of the following: <ol style="list-style-type: none"> a. History of either failure after 4 weeks, contraindication, or intolerance to THREE of the following oral atypical antipsychotics: <ol style="list-style-type: none"> i. Aripiprazole ii. Asenapine iii. Lurasidone iv. Olanzapine v. Paliperidone or Risperidone vi. Quetiapine vii. Ziprasidone b. Documentation that client has been taking cariprazine and is stabilized on the requested dose 3. Client has a CrCl >30mL/min

	<p>4. Client has no history of cirrhosis OR a Child Pugh Score <10</p> <p>If ALL criteria are met, approve for 6 months.</p> <p>Criteria (Reauthorization)</p> <p>Cariprazine may be reauthorized when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. Documentation that client is adherent and stabilized on cariprazine <p>If ALL criteria are met, approve for 12 months.</p>
<p>Depressed bipolar I disorder</p>	<p>Cariprazine may be covered when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. Client is 18 years of age or older 2. Client meets ONE of the following: <ol style="list-style-type: none"> a. History of either failure after 4 weeks, contraindication, or intolerance to THREE of the following oral atypical antipsychotics: <ol style="list-style-type: none"> i. Lurasidone ii. Olanzapine iii. Quetiapine b. Documentation that client has been taking cariprazine and is stabilized at the requested dose 3. Client has a CrCl >30mL/min 4. Client has no history of cirrhosis OR a Child Pugh Score <10 <p>If ALL criteria are met, approve for 6 months.</p> <p>Criteria (Reauthorization)</p> <p>Cariprazine may be reauthorized when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. Documentation that client is adherent and stabilized on cariprazine <p>If ALL criteria are met, approve for 12 months.</p>
<p>Schizophrenia</p>	<p>Cariprazine may be covered when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. Client is 18 years of age or older 2. Client meets ONE of the following: <ol style="list-style-type: none"> a. History of either failure after 4 weeks, contraindication, or intolerance to THREE of the following oral atypical antipsychotic: <ol style="list-style-type: none"> i. Aripiprazole ii. Asenapine iii. Clozapine iv. Iloperidone v. Lurasidone vi. Olanzapine

	<ul style="list-style-type: none"> vii. Paliperidone or Risperidone viii. Quetiapine ix. Ziprasidone <ul style="list-style-type: none"> b. Documentation that client has been taking cariprazine and is stabilized on the requested dose <ul style="list-style-type: none"> 3. Client has a CrCl >30mL/min 4. Client has no history of cirrhosis OR a Child Pugh Score <10 <p>If ALL criteria are met, approve for 6 months.</p>
	Criteria (Reauthorization)
	<p>Cariprazine may be reauthorized when ALL of the following are met:</p> <ul style="list-style-type: none"> 1. Documentation that client is adherent and stabilized on cariprazine <p>If ALL criteria are met, approve for 12 months.</p>

Dosage and quantity limits

Indication	Dose and Quantity Limits
Bipolar I disorder, acute or mixed episodes	<ul style="list-style-type: none"> • Max 6 mg per day; #30 capsules per 30 days
Depressed bipolar I disorder	<ul style="list-style-type: none"> • Max 3 mg per day; #30 capsules per 30 days
Schizophrenia	<ul style="list-style-type: none"> • Max 6 mg per day; #30 capsules per 30 days

Coding:

HCPCS Code	Description
<HCPCS Code>	

References

- Vraylar [prescribing information]. Revised 05/2019. <https://www.accessdata.fda.gov/>
- Aripiprazole [prescribing information]. Revised 12/2014. <https://www.accessdata.fda.gov/>
- Saphris [prescribing information]. Revised 01/2017. <https://www.accessdata.fda.gov/>
- Fanapt [prescribing information]. Revised 05/2009. <https://www.accessdata.fda.gov/>
- Latuda [prescribing information]. Revised 2013. <https://www.accessdata.fda.gov/>
- Olanzapine [prescribing information]. <https://www.accessdata.fda.gov/>
- Quetiapine [prescribing information]. <https://www.accessdata.fda.gov/>
- Ziprasidone [prescribing information]. Revised 12/2014. <https://www.accessdata.fda.gov/>
- Durgam S., Earley W., Lipschitz A., et al. An 8-Week Randomized, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of Cariprazine in Patients with Bipolar I Depression. *Am J Psychiatry*. March 2016. 173(3):271-280.
- Durgam S., Earley W., Li R., et al. Long-term cariprazine treatment for the prevention of relapse in patients with schizophrenia: A randomized, double-blind, placebo-controlled trial. *Schizophrenia Research*. 2016. 176:264-271.
- Earley W., Burgess M., Rekedal L., et al. Cariprazine Treatment of Bipolar Depression: A Randomized Double-Blind Placebo-Controlled Phase 3 Study. *Am J Psychiatry*. 2019. 176(6):439-448.

12. Calabrese J., Keck P., Starace A., et al. Efficacy and Safety of Low- and High-Dose Cariprazine in Acute and Mixed Mania Associated with Bipolar I Disorder: A Double-Blind, Placebo-Controlled Study. *J Clin Psychiatry*. 2015. 76(3):284-292.
13. Nemeth G., Laslovszky I., Czobor P., et al. Cariprazine versus risperidone monotherapy for treatment of predominant negative symptoms in patients with schizophrenia: a randomized, double-blind, controlled trial. *Lancet*. 2017. 389:1103-1113.
14. The American Psychiatric Association Practice Guideline for the Treatment of Patients with Schizophrenia. American Psychiatric Association. 2019.
15. Yatham L., Kennedy S., Parikh S., et al. Canadian Network for Mood and Anxiety Treatments (CANMAT) and International Society for Bipolar (ISBD) 2018 guidelines for the management of patients with bipolar disorder. *Bipolar Disorders*. 2018; 20:97-170.
16. Micromedex® 2.0, (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com> (cited: 06/02/2020).

History

Date	Action and Summary of Changes
05/11/2020	New policy

Antipsychotics – 2nd Generation: cariprazine (Vraylar)

Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible to expedite this request. **Without this information, we may deny the request in seven (7) working days.**

Date of request:	Reference #:	MAS:	
Patient	Date of birth	ProviderOne ID	
Pharmacy name	Pharmacy NPI	Telephone number	Fax number
Prescriber	Prescriber NPI	Telephone number	Fax number
Medication and strength		Directions for use	Qty/Days supply

- Is this request for continuation of existing therapy? Yes No
If yes, is patient is adherent and stabilized on the requested dose? Yes No
- Indicate the patient's diagnosis:
 - Bipolar I Disorder, acute mixed or manic episodes
 - Depressed bipolar I disorder
 - Schizophrenia
 - Other. Specify:
- Does patient have a history of failure after 4 weeks, a contraindication, or intolerance to any of the following oral atypical antipsychotics? (check all that apply)

<input type="checkbox"/> Aripiprazole	<input type="checkbox"/> Asenapine	<input type="checkbox"/> Clozapine	<input type="checkbox"/> Iloperidone
<input type="checkbox"/> Lurasidone	<input type="checkbox"/> Olanzapine	<input type="checkbox"/> Paliperidone	<input type="checkbox"/> Quetiapine
<input type="checkbox"/> Risperidone	<input type="checkbox"/> Ziprasidone	<input type="checkbox"/> Other. Specify:	
- Does patient have severe renal impairment (CrCl <30mL/min)? Yes No
- Does patient have severe hepatic impairment (Child-Pugh ≥10)? Yes No
- Does patient have a history of cirrhosis? Yes No

CHART NOTES ARE REQUIRED WITH THIS REQUEST

Prescriber signature	Prescriber specialty	Date
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