Antipsychotics – 2nd Generation: Vraylar

WA.PHAR.105 Antipsychotics- 2nd Generation Vraylar
Effective Date: March 1, 2021

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.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit:
https://pharmacy.envolvehealth.com/content/dam/centene/envolve-pharmacy-solutions/pdfs/PDL/FORMULARY-CoordinatedCare_Washington.pdf

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: • 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: 1. Client is 18 years of age or older 2. Clients 17 years of age or younger require a second opinion review with the agency-designated mental health specialist from the Second Opinion Network (SON) 3. Client meets **ONE** of the following: a. History of either failure after 4 weeks, contraindication, or intolerance to **THREE** of the following oral atypical antipsychotics: i. Aripiprazole ii. Asenapine iii. Olanzapine

	iv. Paliperidone or Risperidone v. Quetiapine vi. Ziprasidone b. Documentation that client has been taking cariprazine and is stabilized on the requested dose 4. Client has a CrCl >30mL/min 5. Client has no severe hepatic impairment (Child Pugh Score ≥10) If **ALL** criteria are met, approve for 6 months. If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to the initial authorization duration.
	Criteria (Reauthorization) Cariprazine may be reauthorized when **ALL** of the following are met: 1. Documentation that client is stabilized on cariprazine If **ALL** criteria are met, approve for 12 months. If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to the reauthorization duration.
Depressed bipolar I disorder	Cariprazine may be covered when **ALL** of the following are met: 1. Client is 18 years of age or older 2. Clients 17 years of age or younger require a second opinion review with the agency-designated mental health specialist from the Second Opinion Network (SON) 3. Client meets **ONE** of the following: a. History of either failure after 4 weeks, contraindication, or intolerance to **THREE** of the following oral atypical antipsychotics: i. Lurasidone ii. Olanzapine+Fluoxetine (Combination product or individual products taken concurrently) iii. Quetiapine b. Documentation that client has been taking cariprazine and is stabilized at the requested dose 4. Client has a CrCl >30mL/min 5. Client has no severe hepatic impairment (Child Pugh Score ≥10) If **ALL** criteria are met, approve for 6 months. If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to the initial authorization duration.

	Criteria (Reauthorization) Cariprazine may be reauthorized when **ALL** of the following are met: 1. Documentation that client is stabilized on cariprazine If **ALL** criteria are met, approve for 12 months. If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to the reauthorization duration.
Schizophrenia	Cariprazine may be covered when **ALL** of the following are met: 1. Client is 18 years of age or older 2. Clients 17 years of age or younger require a second opinion review with the agency-designated mental health specialist from the Second Opinion Network (SON) 3. Client meets **ONE** of the following: a. History of either failure after 4 weeks, contraindication, or intolerance to **THREE** of the following oral atypical antipsychotic: i. Aripiprazole ii. Asenapine iii. Clozapine iv. Iloperidone v. Lurasidone vi. Olanzapine vii. Paliperidone or Risperidone viii. Quetiapine ix. Ziprasidone b. Documentation that client has been taking cariprazine and is stabilized on the requested dose 4. Client has a CrCl >30mL/min 5. Client has no severe hepatic impairment (Child Pugh Score ≥10) If **ALL** criteria are met, approve for 6 months. If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to the initial authorization duration. **Criteria (Reauthorization)** Cariprazine may be reauthorized when **ALL** of the following are met: 1. Documentation that client is stabilized on cariprazine If **ALL** criteria are met, approve for 12 months.

	If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to the reauthorization duration.

Dosage and quantity limits

Indication	Dose and Quantity Limits
Bipolar I disorder, acute or mixed episodes	• Max 6 mg per day; #30 capsules per 30 days
Depressed bipolar I disorder	• Max 3 mg per day; #30 capsules per 30 days
Schizophrenia	• Max 6 mg per day; #30 capsules per 30 days

References

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History

Date	Action and Summary of Changes
12/15/2020	Added language to clinical criteria sections: Clients 17 years of age or younger require a second opinion review with the agency-designated mental health specialist from the Second Opinion Network (SON)
11/30/2020	Added link to AHPDL publication
11/12/2020	Added language in clinical policy section for cases which do not meet policy criteria
09/01/2020	Updated clinical criteria using feedback from DUR meeting.
08/19/2020	Approved by DUR Board
05/11/2020	New policy