Washington State Health Care Authority

Antipsychotics – 2nd Generation: Vraylar

Medical policy no. 59.40.00.18-2 Effective Date: 10/1/2026

Related medical policies:

Policy Number	Policy Name
N/A	N/A

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://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

Medical necessity

Drug	*Medical Necessity*
cariprazine (Vraylar)	**cariprazine (Vraylar)** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. • Non-Preferred brand name products on the Apple Health Drug List with an A-rated generic, biosimilar or interchangeable biosimilar must also meet criteria in Non-Clinical Policy No 0001 (NC-001). If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health.

Clinical policy:

Clinical Criteria	
Bipolar I Disorder, acute mixed or manic episodes cariprazine (Vraylar)	Cariprazine (Vraylar) may be covered when **ALL** of the following documented criteria are met: 1. Patients 9 years of age or younger require a second opinion review with the agency-designated mental health specialist from the Second Opinion Network (SON)**; OR**

	2. Patient is 10 years of age or older; **AND** 3. Patient meets **ONE** of the following: a. History of failure after 4 weeks to **ONE** of the following oral atypical antipsychotics unless all are contraindicated, or not tolerated: i. Aripiprazole ii. Asenapine iii. Olanzapine iv. Paliperidone v. Quetiapine vi. Risperidone vii. Ziprasidone; **OR** b. Documentation that patient has been taking cariprazine at the requested dose If **ALL** criteria are met, approve for 12 months. **Criteria (Reauthorization)** Cariprazine (Vraylar) may be reauthorized when **ALL** of the following documented criteria are met: 1. Documentation that patient is taking cariprazine If **ALL** criteria are met, approve for 12 months.
Bipolar I Depression cariprazine (Vraylar)	Cariprazine (Vraylar) may be covered when **ALL** of the following documented criteria are met: 1. Patients 17 years of age or younger require a second opinion review with the agency-designated mental health specialist from the Second Opinion Network (SON); **OR** 2. Patient is 18 years of age or older; **AND** 3. Patient meets **ONE** of the following: a. History of failure after 4 weeks to **ONE** of the following oral atypical antipsychotics unless all are contraindicated, or not tolerated: i. Lurasidone ii. Olanzapine+Fluoxetine (combination product or individual products taken concurrently) iii. Quetiapine; **OR** b. Documentation that patient has been taking cariprazine at the requested dose If **ALL** criteria are met, approve for 12 months. **Criteria (Reauthorization)**

	Cariprazine (Vraylar) may be reauthorized when **ALL** of the following documented criteria are met: 1. Documentation that patient is taking cariprazine If **ALL** criteria are met, approve for 12 months.
Schizophrenia cariprazine (Vraylar)	Cariprazine (Vraylar) may be covered when **ALL** of the following documented criteria are met: 1. Patients 12 years of age or younger require a second opinion review with the agency-designated mental health specialist from the Second Opinion Network (SON). 2. Patient is 13 years of age or older; **AND** 3. Patient meets **ONE** of the following: a. History of failure after 4 weeks, to **ONE** of the following oral atypical antipsychotics unless all are contraindicated, or not tolerated: i. Aripiprazole ii. Asenapine iii. Clozapine iv. Iloperidone v. Lurasidone vi. Olanzapine vii. Paliperidone viii. Quetiapine ix. Risperidone x. Ziprasidone; **OR** b. Documentation that patient has been taking cariprazine at the requested dose If **ALL** criteria are met, approve for 12 months.
	Criteria (Reauthorization)
	Cariprazine (Vraylar) may be reauthorized when **ALL** of the following documented are met: 1. Documentation that patient is taking cariprazine If **ALL** criteria are met, approve for 12 months.
Major Depressive Disorder (MDD), adjunct therapy to antidepressants cariprazine (Vraylar)	Cariprazine (Vraylar) may be covered when **ALL** of the following documented criteria are met: 1. Patients 17 years of age or younger require a second opinion review with the agency-designated mental health specialist from the Second Opinion Network (SON); **OR** 2. Patient is 18 years of age or older; **AND**

	3. Patient meets **ONE** of the following: a. History of failure after 4 weeks, to **TWO** of the following oral antidepressants unless all are contraindicated, or not tolerated: i. Bupropion ii. Citalopram iii. Desvenlafaxine iv. Duloxetine v. Escitalopram vi. Fluoxetine vii. Fluvoxamine viii. Mirtazapine ix. Paroxetine x. Sertraline xi. Venlafaxine xii. Vortioxetine; **OR** b. Documentation that patient has been taking cariprazine at the requested dose; **AND** Cariprazine will be used with an antidepressant If **ALL** criteria are met, approve for 12 months.
	Criteria (Reauthorization) Cariprazine (Vraylar) may be reauthorized when **ALL** of the following documented criteria are met: 1. Documentation that patient is taking cariprazine; **AND** 2. Continued use of an antidepressant. If **ALL** criteria are met, approve for 12 months.

Dosage and quantity limits

Drug	Indication	Approved Dose	Dosage Form and Quantity Limit
Cariprazine (Vraylar)	Bipolar I disorder, acute or mixed episodes	10 - 17 years of age - Max 4.5 mg per day 18 years of age and older -Max 6 mg per day	• 30 capsules per 30 days
	Bipolar I depression	18 years of age and older -Max 3 mg per day	• 30 capsules per 30 days
	Schizophrenia	13 - 17 years of age - Max 4.5 mg per day	• 30 capsules per 30 days

		18 years of age and older -Max 6 mg per day	
	Major Depressive Disorder	18 years of age and older -Max 3 mg per day	• 30 capsules per 30 days

Coding:

HCPCS Code	Description
N/A	N/A

References

1. Vraylar [prescribing information]. Revised 12/2025.
2. Aripiprazole [prescribing information]. Revised 12/2014.
3. Saphris [prescribing information]. Revised 01/2017.
4. Fanapt [prescribing information]. Revised 05/2009.
5. Latuda prescribing information]. Revised 2013.
6. Olanzapine [prescribing information].
7. Quetiapine [prescribing information].
8. Ziprasidone [prescribing information]. Revised 12/2014.
9. 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.
10. 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.
11. Earley W., Burgess M., Rekeda 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

Approved Date	Effective Date	Version	Action and Summary of Changes
06/09/2026	10/1/2026	59.40.00.18-2	-Updated the indications for bipolar disorder, bipolar depression, and schizophrenia

			-Added indication of MDD, adjunct therapy to antidepressant. -Updated the Dosage and quantity limits table

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