Clinical Policy: Cariprazine (Vraylar)

Reference Number: AZ.CP.PHAR.10.11.12
Effective Date: 08.08.2017
Last Review Date: 07.18
Line of Business: Arizona Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Cariprazine (Vraylar®) is an atypical antipsychotics.

FDA Approved Indication(s)
Vraylar is indicated for the treatment of:
- Schizophrenia
- Manic or mixed episodes associated with bipolar I disorder.

Policy/Criteria
Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Vraylar is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Bipolar Disorder and Schizophrenia (must meet all)**:**

1. Diagnosis of bipolar disorder or schizophrenia spectrum disorder ((schizophrenia, schizoaffective disorder, schizophreniform disorders)
2. Age ≥ 18 years;
3. Failure of 3 preferred atypical antipsychotics, one of which must be aripiprazole, at up to maximally indicated doses each trialed for ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 6 mg per day (1 capsule/day).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Vraylar for bipolar or schizophrenia spectrum disorder and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 6 mg per day (1 capsule/day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy-CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

Not applicable

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
aripiprazole (Abilify®)	10-30 mg by mouth daily	30 mg/day
Clozapine	12.5 mg-450 mg in divided doses	900 mg/day
ziprasidone (Geodon®)	40-80 mg by mouth twice daily	160 mg/day
Latuda® (lurasidone)	40 mg- 160 mg once daily with food.	160 mg/day
risperidone (Risperdal®)	1-4 mg by mouth daily to twice daily	16 mg/day
Quetiapine (Seroquel®)	400-800 mg/day by mouth twice daily to three times daily in divided doses	800 mg/day
olanzapine (Zyprexa®)	10-20 mg by mouth daily	20 mg/day

Saphris® (asenapine)	5-10 mg twice daily	20 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: General Information

Schizophrenia Spectrum and other psychotic disorders include schizophrenia, and other psychotic disorders and schizotypal (personality) disorder. They are defined by abnormalities in one or more of the following 5 domains: Delusions, hallucinations, disorganized thinking, grossly disorganized or abnormal motor behavior including catatonia, and negative symptoms.

Vraylar and aripiprazole are both dopamine partial agonists.

Vraylar has a black box warning for increased mortality in elderly patients with dementia-related psychosis. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Vraylar is not approved for the treatment of patients with - dementia-related psychosis.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Schizophrenia	1.5 mg to 6 mg once per day	6 mg per day
Bipolar Mania	3 mg to 6 mg once per day	6 mg per day

VI. Product Availability

Capsules: 1.5 mg, 3 mg, 4.5 mg, and 6 mg

VII. References

1. Cariparazine Drug Monograph. Clinical Pharmacology. Accessed May 2018. http://www.clinicalpharmacology-ip.com
2. Vraylar Prescribing Information. Irvine, CA: Allergan USA, Inc.; February 2017. Available at: http://www.vraylar.com/. Accessed November 2, 2017.
3. Lehman AF, Lieberman JA, Dixon LB et al. Practice guideline for the treatment of patients with schizophrenia, second edition. Am J Psychiatry. 2004 Feb;161(2 Suppl):1-56.
4. American Psychiatric Association. Practice guideline for the treatment of patients with bipolar disorder. Am J Psychiatry. 2002 Apr;159(4 Suppl):1-50.
5. American Psychiatric Association Practice Guideline for the Treatment of Patients with Bipolar Disorder: Second Edition (2010). Available at: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf. Accessed online May 2018.
6. American Psychiatric Association: Guideline Watch (September 2009): Practice Guideline for the Treatment of Patients with Schizophrenia, 2009. http://psychiatryonline.org/guidelines. Accessed May 2018

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Updated references	05/18	07/18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.