



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 3072-8
Program	Step Therapy
Medication	Vraylar (cariprazine)
P&T Approval Date	4/2016, 5/2017, 5/2018, 5/2019, 5/2020
Effective Date	8/1/2020; Oxford only: 8/1/2020

1. Background:

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. Vraylar (cariprazine) is FDA approved for the acute treatment of manic or mixed episodes associated with bipolar I disorder, for the treatment of depressive episodes associated with bipolar I disorder, and for the treatment of schizophrenia.

For the treatment of schizophrenia, treatment guidelines recommend the use of any atypical antipsychotic (with the exception of clozapine) as first-line. For the acute treatment of bipolar I disorder (mania or mixed episodes), the American Psychiatric Association (APA) recommends treatment with lithium plus an antipsychotic or valproate plus an antipsychotic. For less ill patients, monotherapy with lithium, valproate, or an antipsychotic may be sufficient. Atypical antipsychotics are generally preferred over traditional antipsychotics.

This program requires a member to try two atypical antipsychotics (choices include aripiprazole, risperidone, olanzapine, ziprasidone, quetiapine IR or quetiapine ER) before providing coverage for Vraylar for schizophrenia or bipolar I disorder.

2. Coverage Criteria^a:

A. Initial Authorization

1. **Vraylar** will be approved based **one** of the following criteria:

a. History of failure, contraindication, or intolerance to **at least two** of the following (please document drug, date and duration of trial):

- (1) aripiprazole
- (2) olanzapine
- (3) quetiapine IR or ER
- (4) risperidone
- (5) ziprasidone

-OR-

- b. Treatment with Vraylar was initiated at a recent behavioral inpatient admission (discharge within the past 3 months) and the member is currently stable on therapy. (Please document date of discharge from inpatient admission).

Authorization will be issued for 12 months.

B. Reauthorization

1. **Vraylar** will be approved based on the following criterion:
- a. Documentation of positive clinical response to therapy

Reauthorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may also be in place.

4. References:

1. Vraylar [Prescribing Information]. Madison, NJ:Allergan USA, Inc.; May 2019.
2. American Psychiatric Association. Practice Guideline for the Treatment of Patients with Schizophrenia Second Edition. Available at: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf
3. American Psychiatric Association. Practice Guideline for the Treatment of Patients with Bipolar Disorder, Second Edition. Available at: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf

Program	Step Therapy - Vraylar (cariprazine)
Change Control	
4/2016	New program.
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
5/2017	Annual Review. Changed brand Seroquel XR to generic formulation and updated references. Updated state mandate reference language.



5/2018	Annual review. Updated references.
12/2018	Administrative change to add statement regarding use of automated processes.
5/2019	Annual review. No updates.
5/2020	Annual review. Combined quetiapine IR and ER into one Step One option. Added reauthorization criteria. Updated references.