

# BC PharmaCare Drug Information

The drug below is being considered for possible coverage under the B.C. PharmaCare program. PharmaCare is a government-funded drug plan that helps British Columbians with the cost of eligible prescription drugs and specific medical supplies. For more information on PharmaCare, visit Ministry of Health - PharmaCare.

PharmaCare reviews each drug for treating a specific illness or medical condition (known as an "indication"). If a decision is made to cover the drug, it will be only for that illness or condition.

In some cases, PharmaCare may cover a drug only for people who have the illness or condition and have not responded to other drugs used to treat that illness or condition.

For more information on PharmaCare's drug coverage review process, see the last page of this information sheet.

Information about the drug					
Generic name (scientific name)	cariprazine				
Brand name	Vraylar <sup>®</sup>				
Manufacturer	Allergan (an AbbVie Company)				
Indication	Bipolar disorder				
Has the drug been reviewed by the Common Drug Review (CDR)? (see the note below this table.)	Yes For more information about the CDR's review of cariprazine (Vraylar), you can <u>Search</u> the CDR Reports.				
Public input start date	Wednesday, May 25, 2022				
Public input closing date	Wednesday, June 22, 2022, AT MIDNIGHT				
How is the drug taken?	Cariprazine is taken orally (by the mouth).				
How often is the drug taken?	Cariprazine is taken once daily.				

### BC PharmaCare Drug Information —cariprazine (Vraylar®) continued...

# General drug and/or drug study information

Cariprazine (Vraylar) is used to treat bipolar disorder, including both bipolar mania and bipolar depression. Bipolar disorder is a mental health condition that causes extreme mood swings, including emotional highs (mania and/or hypomania) and emotional lows (depression). Bipolar mania is more severe than hypomania, but both kinds of episodes include three or more of the following symptoms:

- Feeling abnormally upbeat, jumpy or wired
- Increased activity, energy or agitation
- Exaggerated sense of well-being and self-confidence (euphoria)
- Decreased need for sleep
- Unusual talkativeness
- Racing thoughts
- Distractibility
- Poor decision-making for example, going on buying sprees, taking sexual risks, or making foolish investments

Bipolar depressive episodes include five or more of the following symptoms:

- Depressed mood, such as feeling sad, empty, hopeless or tearful
- Loss of interest or feeling no pleasure in all or almost all activities
- Significant weight loss when not dieting, weight gain, or decrease or increase in appetite
- Either insomnia or sleeping too much
- Either restlessness or slowed behavior
- Fatigue or loss of energy
- Feelings of worthlessness or excessive or inappropriate guilt
- Decreased ability to think or concentrate, or indecisiveness
- Thinking about, planning or attempting suicide

Cariprazine belongs to a group of medicines called atypical antipsychotics drugs. Antipsychotic medications affect the chemicals (neurotransmitters) that allow nerve cells to talk to each other. Two of the chemicals in the brain, called dopamine and serotonin, may be out of balance in bipolar depression. It is not known exactly how cariprazine works. However, it seems to help keep the right balance of dopamine and serotonin in your brain.

Studies looked at the following:

- Efficacy and safety, of cariprazine versus placebo (sugar pill)
- Changes from baseline in the Young Mania Rating Scale (YMRS) Total Score.
   The YMRS is a multiple choice questionnaire used by psychiatrists to measure the presence and severity of mania symptoms.
- Changes from baseline in the Clinical Global Impression: Severity (CGI-S) Total Score. The CGI-S scale is a tool used by doctors to measure and track symptom severity.
- Changes from baseline in the Montgomery–Åsberg Depression Rating Scale
  (MADRS) total score. The MADRS is a questionnaire which psychiatrists use to
  measure the severity of depressive episodes in patients with mood disorders.

Information about the drug					
	<ul> <li>Bad reactions</li> <li>Serious bad reactions</li> <li>Patients leaving the trial due to bad reactions</li> <li>Bad reactions of special interest (thoughts of suicide, inability to sit still, involuntary muscle contractions, tremors, stiff muscles, and involuntary facial movements, insomnia, sedation, metabolism and nutrition disorders, increased blood glucose, weight gain, restlessness, vomiting, decreased interest in sex, involuntary movement of the face, neck, arms, and legs, and neuroleptic maliganant syndrome (NMS), a rare reaction to antipsychotic drugs)</li> </ul>				
Other considerations					

### Note:

The Common Drug Review (CDR) is a national organization that reviews drugs on behalf of Canadian public sector plans when manufacturers want to have the jurisdictions provide coverage for the drugs. For detailed information on B.C. PharmaCare's drug review process, including the role of the CDR in that process, see <a href="https://example.com/The Drug Review Process in B.C. - Overview">The Drug Review Process in B.C. - Overview</a>.

Cost of the drug under review compared to other drugs used to treat the same indication							
generic name (Brand Name) of Drug Comparator	PharmaCare Status (if and how the drug is already covered)	Dosage Form	Usual Dose	Annual Cost of Therapy <sup>a</sup>			
cariprazine (Vraylar)	Under Review	Capsule	Once daily	\$1,932 <sup>b</sup>			
First- line therapies	First- line therapies						
aripiprazole (generics)	Limited Coverage for the treatment of schizophrenia or other psychosis (not dementia related), subject to LCA	Tablet	Once daily	\$395 to \$424			
divalproex (generics)	Regular Benefit, subject to <u>LCA</u>	Tablet	Three times daily	\$327			
lithium (generics)	Regular Benefit, subject to <u>LCA</u>	Capsule	Once daily	\$78 to \$235			
paliperidone (Invega)	Regular Benefit	Extended release (ER) Tablet	Once daily	\$2,348			

<sup>&</sup>lt;sup>a</sup> All prices as per B.C. PharmaCare Formulary, unless otherwise specified.

<sup>&</sup>lt;sup>b</sup> Manufacturer's submitted price plus 8% markup.

## BC PharmaCare Drug Information —cariprazine (Vraylar®) continued...

Cost of the drug under review compared to other drugs used to treat the same indication						
generic name (Brand Name) of Drug Comparator	PharmaCare Status (if and how the drug is already covered)	Dosage Form	Usual Dose	Annual Cost of Therapy <sup>a</sup>		
quetiapine (generics)	Regular Benefit, subject to <u>LCA</u>	Extended release (ER) tablet and regular tablet	Once daily	\$209 to \$1,046		
risperidone (generics)	Regular Benefit	Tablet	Once daily	\$94 to \$377		
Second- line therapies						
carbamazepine (generics)	Regular Benefit, subject to <u>LCA</u>	Tablet	Once daily	\$202 to \$606		
olanzapine (generics)	Limited Coverage for the treatment of schizophrenia or other psychosis (not dementia related), subject to LCA	Tablet	Once daily	\$141 to \$557		
ziprasidone (generics)	Limited Coverage for the treatment of schizophrenia or other psychosis (not dementia related), subject to LCA	Capsule	Twice daily	\$1,233		
Third- line therapies						
chlorpromazine (generic)	Regular Benefit	Tablet	Once daily	\$426		
clonazepam (generics)	Regular Benefit, subject to <u>LCA</u>	Tablet	Once daily	\$114 to \$142		

### The Drug Review Process in B.C.

A manufacturer submits a request to the Ministry of Health (Ministry).

An independent group called the <u>Drug Benefit Council (DBC)</u> gives advice to the Ministry. The DBC looks at:

- whether the drug is safe and effective
- advice from a national group called the Common Drug Review (CDR)
- what the drug costs and whether it is a good value for the people of B.C.
- ethical considerations involved with covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes PharmaCare coverage decisions by taking into account:

- the existing PharmaCare policies, programs and resources
- the evidence-informed advice of the DBC
- the drugs already covered by PharmaCare that are used to treat similar medical conditions
- the overall cost of covering the drug

For more information about the B.C. Drug Review Process, visit: The Drug Review Process in B.C. - Overview.

### This document is intended for information only.

It does not take the place of advice from a physician or other qualified health care provider.