

Drug Coverage Decision for B.C. PharmaCare

About PharmaCare B.C. PharmaCare is a government-funded drug plan. It helps British Columbians with the cost of eligible prescription drugs and specific medical supplies.

Details of Drug Reviewed

Drug	ulipristal
Brand Name	Fibristal®
Dosage Form(s)	5 mg tablet
Manufacturer	Allergan Inc.
Submission Type	New Submission
Use Reviewed	Treatment of uterine fibroids in adult women of reproductive age.
Common Drug Review (CDR)	Yes, CDR recommended for both the new submission and new indication: to Reimburse with clinical criteria and/or conditions , Visit the CDR website for more details: https://www.cadth.ca/sites/default/files/cdr/complete/complete_SR0326_Fibrystal_19-Nov-13_e.pdf Visit the CDR website for more details: https://www.cadth.ca/sites/default/files/cdr/complete/SF0528_Fibrystal_RFA_complete_Nov_22_17.pdf
Drug Benefit Council (DBC)	DBC met on April 14, 2014 and December 4, 2017. DBC considered various inputs including: the final reviews completed by the CDR, which included clinical evidence and pharmacoeconomic reports and the recommendations from CDEC. The DBC also considered Clinical Practice Reviews from two specialists, Patient Input Questionnaire from three patients collected through the Ministry's patient input mechanism, Your Voice, as well as Budget Impact Assessment (BIA).
Drug Coverage Decision	Limited Coverage Benefit for the treatment of uterine fibroids in adult women of reproductive age for a single three-month course of therapy. Access the ulipristal criteria at www.gov.bc.ca/pharmacarespecialauthority
Date	October 2, 2018
Reason(s)	<ul style="list-style-type: none"> Based on two randomized controlled trials (RCTs), the drug was similar to leuprolide and demonstrated some advantage over placebo with respect to efficacy and safety but not quality of life. The RCTs were limited to one three-month treatment course. Based on economic considerations and the submitted product price, the drug was cost-effective comparing with leuprolide for a three-month treatment course. Based on one additional RCT, the drug, when used as intermittent treatment, demonstrated some efficacy. However, the RCT had no control group. BC participated in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer for the use of ulipristal as a single three-month course of therapy.
Other	None

The Drug Review Process in B.C.

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

An independent group called the [Drug Benefit Council \(DBC\)](#) 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

Visit the [The Drug Review Process in B.C. - Overview](#) and [Ministry of Health - PharmaCare](#) for more information.

This document is intended for information only.

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