

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	ezetimibe
Brand Name	Ezetrol and generics
Dosage Form	10 mg tablets
Manufacturer	Merck Canada Inc. and generic manufacturers
Submission Type	Ministry initiated submission
Use Reviewed	Heterozygous Familial Hypercholesterolemia (HeFH) and hypercholesterolemia
Common Drug Review (CDR)	No, CDR did not review ezetimibe.
Drug Benefit Council (DBC)	DBC met on November 5, 2018. DBC considered various inputs including: the results of the Improved Reduction of Outcomes: Vytorin Efficacy International Trial (IMPROVE-IT) published June 3, 2015, in the New England Journal of Medicine; the 2016 Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease in the Adult; a Systematic Literature Review published November 25, 2016, by Australia Centre for Population Health Research; and a Budget Impact Assessment.
Drug Coverage Decision	Limited Coverage. Access the ezetimibe criteria from www.gov.bc.ca/pharmacarespecialauthority Regular Benefit for Plan W
Date	December 18, 2018
Reasons	Drug coverage decision is consistent with the DBC recommendation. <ul style="list-style-type: none"> Ezetimibe, when added to statin therapy, demonstrated advantage over placebo in reducing low density lipoprotein cholesterol (LDL-C) and improved cardiovascular outcomes. Cost of ezetimibe at generic price is similar to cost of least costly statins.
Other Information	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.

Drug Benefit Council (DBC) Recommendation and Reasons for Recommendation

FINAL

Ezetimibe (Ezetrol® and generics)

Merck Canada Inc. and various generic manufacturers

Description:

Drug review of **ezetimibe (Ezetrol® and generics)** for the following Health Canada approved indications:

Heterozygous Familial Hypercholesterolemia (HeFH) and hypercholesterolemia.

In their review, the DBC considered the following: the Ezetrol® product monograph, the results of the Improved Reduction of Outcomes: Vytorin Efficacy International Trial (IMPROVE-IT) published June 3, 2015 in the *New England Journal of Medicine*; the 2016 Canadian Cardiovascular Society *Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease in the Adult*; a Systematic Literature Review published November 25, 2016 by the Centre for Population Health Research; and a Budget Impact Assessment.

The DBC was asked to provide an answer to the question: based on the evidence provided, what is your recommendation to the British Columbia Ministry of Health (the Ministry) regarding the PharmaCare coverage status of ezetimibe (Ezetrol® and generics) for the treatment of:

1. Heterozygous Familial Hypercholesterolemia (HeFH); and
2. hypercholesterolemia

Dosage Forms:

Ezetimibe is available as 10 mg tablet.

Recommendations:

1. The Drug Benefit Council (DBC) recommends that ezetimibe (Ezetrol® and generics) should be listed as a benefit.

Reasons for the Recommendation:

1. Summary

- Ezetimibe monotherapy significantly reduced low density lipoprotein cholesterol (LDL-C) concentrations compared with placebo, and significant potentially favourable changes were also observed in total cholesterol and high density lipoprotein cholesterol (HDL-C).
- When added to statin therapy, ezetimibe resulted in incremental lowering of LDL-C levels and improved cardiovascular outcomes.
- At current manufacturer list prices, the annual cost of ezetimibe monotherapy is similar to most statins and significantly lower than evolocumab and alirocumab. The annual cost of ezetimibe in combination with a statin is still significantly lower than evolocumab and alirocumab.

2. Clinical Efficacy

- The Systematic Literature Review provided by the Centre for Population Health Research (which included meta-analyses of eight studies for LDL-C and nine studies for HDL-C) concluded that ezetimibe monotherapy significantly reduced LDL-C concentrations compared with placebo, and significant potentially favourable changes were also observed in total cholesterol and HDL-C.
- The combination of ezetimibe with a statin significantly reduced LDL-C and significantly increased HDL-C. Results of the studies that up-titrated the statin doses to achieve LDL-C targets generally showed that the co-administration of ezetimibe and statin was more effective in reducing LDL-C than statin monotherapy.

3. Safety

- Ezetimibe monotherapy appeared to be well tolerated with a safety profile similar to placebo. Ezetimibe in combination with a statin has a similar safety profile to a statin monotherapy.

4. Economic Considerations

- At current manufacturer list prices, the annual cost of ezetimibe monotherapy is similar to most statins and significantly lower than evolocumab and alirocumab. The annual cost of ezetimibe in combination with a statin is still significantly lower than evolocumab and alirocumab.
- Listing ezetimibe as a PharmaCare benefit would most likely result in a modest budget impact.

5. Of Note

- Ezetimibe, administered alone or with a statin, is indicated for the reduction of elevated total cholesterol, LDL-C, apolipoprotein B, and triglycerides and to increase HDL-C in patients with primary (heterozygous familial and non-familial) hypercholesterolemia.
- Ezetimibe, administered with a statin, is indicated for the reduction of elevated total cholesterol and LDL-C levels in patients with HoFH as an adjunct to treatments such as LDL apheresis or if such treatments are not possible.