

B.C. Ministry of Health Services Drug Coverage Decision

About PharmaCare	B.C. PharmaCare helps British Columbians with the cost of eligible prescription drugs and specific medical supplies.
PharmaCare Coverage	The Ministry of Health Services (Ministry) makes PharmaCare coverage decisions by considering existing PharmaCare policies, programs and resources and the evidence-based recommendations of an independent advisory body called the Drug Benefit Council (DBC). The DBC's advice to the Ministry is based upon a review of many considerations, including available clinical and pharmacoeconomic evidence, clinical practice and ethical considerations, and the recommendations of the national Common Drug Review, when applicable.
Inside	Page 1 includes the Ministry's decision and reasons in wording that is easier for readers without a medical background to understand. Page 2 summarizes the Drug Benefit Council (DBC) recommendation, the Ministry's decision and the reasons for the Ministry's decision.

Ezetimibe (Ezetrol®) for high cholesterol

Understanding the DBC Recommendation and PharmaCare Coverage Decision

Background

- Cholesterol is a type of fat that comes from the diet but is also made in the body. **High cholesterol** can build up in the blood vessels and make them narrow. This can lead to a heart attack or stroke.
- Cholesterol is found in the body as low-density lipoproteins (LDL), high-density lipoproteins (HDL) and triglycerides (TG). LDL and TG are called "bad cholesterol". HDL is called "good cholesterol" because it helps protect against heart disease.
- Neimann-Pick C1 Like1 (NPC1L1) protein is found in the intestine and helps with the uptake of cholesterol. People have different forms of NPC1L1 protein. Some forms cause people to take in more cholesterol from their diet and other forms cause people to take in less cholesterol from their diet.
- **Ezetimibe** has the brand name **Ezetrol®**.
 - Ezetimibe belongs to the class of drugs called cholesterol absorption inhibitors.
 - Ezetimibe works on the NPC1L1 protein to reduce the amount of cholesterol absorbed from food.
 - Ezetimibe decreases bad cholesterol.

Why was this drug reviewed?

- Drug company request.

What did the review find?

- There are not enough studies to prove that ezetimibe works better or is safer than taking no drug or other drugs used to lower cholesterol.
- There are not enough studies to prove that ezetimibe together with the cholesterol lowering class of drugs called statins works better or is safer than taking only a statin.
- No studies have looked at the long-term effects of ezetimibe on life-span or illnesses. These studies have been done for other classes of drugs used to lower cholesterol.

What decision was made?

- Ezetimibe will not be covered.

Key Term(s)

- No Key term(s)

This document is intended for information only. It does not take the place of advice from a physician or other qualified health care provider.

Please visit us online to find out more about the Pharmaceutical Services Division and the PharmaCare program at www.health.gov.bc.ca/pharmacare. To find out more about how drugs are considered for PharmaCare coverage, visit www.health.gov.bc.ca/pharmacare/formulary.



Ezetimibe (Ezetrol®) for hypercholesterolemia

Drug Class

- Cholesterol absorption inhibitor

Available Dosage Forms

- 10 mg tablets

Sponsor/Requestor

- Merck Frosst-Schering Pharma.

Submission (Request) to PharmaCare

- Resubmission to have ezetimibe covered for the treatment of hypercholesterolemia in patients who are at high risk of cardiovascular disease.

Drug Benefit Council (DBC) Recommendations

- A literature search was performed to identify published double blind randomized controlled trials (DB RCTs) evaluating the following research questions:
 - In adult patients with primary hypercholesterolemia, homozygous familial hypercholesterolemia (HoFH) or sitosterolemia, does ezetimibe monotherapy compared to placebo or monotherapy with another cholesterol lowering drug reduce mortality and/or morbidity?
 - In adult patients with primary hypercholesterolemia, HoFH or sitosterolemia, does ezetimibe in combination with a statin compared to statin monotherapy reduce mortality and/or morbidity?
 - In adult patients with primary hypercholesterolemia, HoFH or sitosterolemia, does ezetimibe in combination with a statin compared to a statin plus another cholesterol lowering drug reduce mortality and/or morbidity?

- In 2005, a systematic review of ezetimibe was performed. In 2007, no new DB RCTs were identified comparing ezetimibe in combination with a statin to a statin plus another cholesterol lowering drug in adult patients with primary hypercholesterolemia, HoFH or sitosterolemia.
- There is insufficient evidence that ezetimibe monotherapy offers a statistically significant and clinically important efficacy or safety advantage over placebo or monotherapy with another cholesterol lowering drug. There is also insufficient evidence that ezetimibe in combination with a statin compared to statin monotherapy offers a statistically significant and clinically important efficacy or safety advantage over statin monotherapy in adult patients with primary hypercholesterolemia, HoFH or sitosterolemia. The effect of cholesterol reduction with ezetimibe on long-term clinically important outcomes has not been assessed and more data exists in this area for other available classes of cholesterol lowering medications.

Decision and Status

- Not a benefit.
- Effective September 27, 2007

Key Term(s)

- No Key Term(s)