

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 decision and reasons in wording that is easier for readers without a medical background to understand. **Page 2** summarizes the DBC recommendation, the Ministry's decision and the reasons for the Ministry's decision.

Niacin extended-release plus lovastatin (Advicor®) 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.
- The combination of **niacin plus lovastatin** in a single tablet has the brand name **Advicor®**.
 - **Niacin** is also called vitamin B₃. In this combination tablet, niacin is in a long-acting form. This means that niacin is slowly released from the tablet.
 - **Lovastatin** is part of the group of drugs called the HMG-CoA reductase inhibitors.
- 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 the body clear cholesterol.
- Niacin plus lovastatin together decrease bad cholesterol and increase good cholesterol. This can decrease the risk for heart attack or stroke.

Why was this drug reviewed?

- Drug company request.

What did the review find?

- Studies show that using these two drugs combined works better than using either drug alone.
- The side effects of the two drugs combined are much the same as side effects of using either drug alone.
- Niacin extended-release causes less redness and hot feeling of the face compared to regular niacin. It is not known if niacin extended-release is safer than regular niacin.
- Side effects of the two drugs in combination may include damage to the liver and muscle cells.
- Regular niacin is already covered by PharmaCare, but niacin extended-release is not covered. There will likely be no change in the overall cost to the Ministry if the combination product is covered.

What decision was made?

- Niacin extended-release plus lovastatin will be covered as a **regular benefit**.

Key Term

- **Regular benefits** are prescription drugs that are covered according to the rules of a patient's PharmaCare plan including any annual deductible requirement. Patients do not need Special Authority from PharmaCare for coverage of these drugs.

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/pharme. To find out more about how drugs are considered for PharmaCare coverage, visit www.health.gov.bc.ca/pharme/formulary.



Niacin extended-release plus lovastatin (Advicor®) for hypercholesterolemia

Drug Class

- Niacin (vitamin B₃) plus HMG-CoA reductase inhibitor

Available Dosage Forms

- 500 mg/20 mg and 1000 mg/20 mg extended-release tablets (combination product niacin extended-release/lovastatin)

Sponsor/Requestor

- Oryx Pharmaceuticals Inc.

Submission (Request) to PharmaCare

- Health Canada has approved niacin extended-release plus lovastatin combined for the treatment of primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Frederickson Type IIa and IIb) in:
 - Patients treated with lovastatin requiring further reduction of triglycerides (TG) or elevation of high-density lipoprotein (HDL) cholesterol, who may benefit from niacin added to their regimen, **and**
 - Patients treated with extended-release niacin requiring further reduction of low-density lipoprotein (LDL) cholesterol, who may benefit from having lovastatin added to their regimen.
- There is sufficient evidence that niacin extended-release plus lovastatin provides a significant reduction of TG, elevation of HDL cholesterol, and a similar reduction of LDL cholesterol compared to lovastatin alone.
- There is sufficient evidence that niacin extended-release plus lovastatin provides a significant reduction of LDL cholesterol and TG, and an elevation of HDL cholesterol compared to niacin alone.
- Adverse effects with the niacin extended-release plus lovastatin are similar to those seen with the each drug alone.
- Niacin extended-release is associated with a reduced number of episodes of short-term flushing compared to immediate release niacin, but the long-term clinical significance is unknown.
- Hepatic toxicity, myopathy and rhabdomyolysis are adverse effects associated with niacin extended-release plus lovastatin.
- The Ministry currently does not provide coverage for niacin extended-release, but it does provide coverage for regular-release niacin.
- Listing of niacin extended-release plus lovastatin will likely be cost-neutral to the Ministry.

Drug Benefit Council (DBC) Recommendation

- Niacin extended-release plus lovastatin be listed as a regular benefit

Reasons for the Ministry of Health Services Decision

- A literature search identified two randomized controlled trials (RCTs) comparing the niacin extended-release plus lovastatin combination versus lovastatin monotherapy and niacin monotherapy.

Decision and Status

- **Regular benefit**
- Effective March 3, 2008

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