

B.C. Ministry of Health Services Drug Coverage Decisions

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 DBC recommendation, the Ministry's decision and the reasons for the Ministry's decision.

Telbivudine (Sebivo®) for chronic hepatitis B infection in patients with liver damage

Understanding the DBC Recommendation and PharmaCare Coverage Decision

Background

- **Hepatitis B** is an infection of the liver caused by a virus. It is spread by contact with blood and body fluids of infected people (e.g. during sex, sharing needles or passing from mother to child during birth).
- New infections do not usually require treatment because most adults clear the infection on their own. However, some patients develop chronic hepatitis B after 6 months. **Chronic infections** can lead to liver damage or scarring (cirrhosis) and liver cancer.
- **Antiviral drugs** are used to treat some patients with chronic hepatitis B. The goal of treatment is to stop the virus from growing and to stop the progress of liver damage. **Resistance** occurs when the antiviral is no longer effective.
- **Telbivudine** has the trade name **Sebivo®**. It is an antiviral and belongs to the class of drugs called **nucleosides and nucleotides**.
 - It is used to treat chronic hepatitis B in adults with liver damage.
 - Telbivudine prevents the virus from growing and infecting new liver cells.
- **Lamivudine** is another antiviral used to treat hepatitis B, and is a limited coverage benefit.

Why was this drug reviewed?

- Drug company request.

What did the review find?

- One study shows that telbivudine may be better than lamivudine for treating chronic hepatitis B with liver damage. The results of this study were based on lab tests only. The study did not show a difference in cure rate.
- Studies suggest that a large number of people will develop resistance to telbivudine after starting therapy.
- The most common side effect is an abnormal blood test that measures muscle breakdown. Compared to lamivudine, there are no differences in serious side effects or stopping therapy due to side effects.
- Telbivudine costs more than lamivudine, which is listed as a limited coverage benefit for chronic hepatitis B. It is uncertain whether telbivudine is cost-effective overall.

What decision was made?

- Telbivudine will **not be covered**.

Key Term (s)

- **Limited coverage** drugs are not normally considered the first choice in treatment, or other drugs may offer better value. To receive coverage, the patient's physician must submit a Special Authority request to PharmaCare. If the request is approved, the drug is covered up to the usual PharmaCare coverage limits. Actual reimbursement depends on the rules of a patient's PharmaCare plan including any annual deductible requirement.

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.



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Telbivudine (Sebivo®) for chronic hepatitis B infection in patients with liver disease

Drug Class

- Nucleosides and nucleotides

Available Dosage Forms

- 600 mg tablet

Sponsor/Requestor

- Novartis Pharmaceutical Canada Inc.

Submission (Request) to PharmaCare

- Drug review of telbivudine for the following Health Canada approved indication:
 - Treatment of chronic hepatitis B (HBV) infections in adults 16 years and older with compensated liver disease and evidence of viral replication and active liver inflammation.

Drug Benefit Council (DBC) Recommendations

- That telbivudine (Sebivo®) not be covered.

Reasons for the Ministry of Health Services Decision

- Four randomized controlled trials (RCTs) were identified that compared telbivudine with lamivudine in nucleos(t)ide-naïve patients with compensated liver disease. There was no trial comparing telbivudine to other therapies in lamivudine-resistant patients. One of the trials was small and two trials are still ongoing, so the review focused on the largest RCT, which evaluated histological, virological and biochemical surrogate markers.
- In hepatitis B surface antigen (HBeAg) positive patients, telbivudine resulted in a statistically significant increase in the proportion of patients with undetectable HBV DNA (NNT=6), normalization of alanine aminotransferase (NNT=13) and a decrease in the number of patients who developed virologic breakthrough (19% telbivudine, 33% lamivudine).

- There was no statistically significant difference in the rate of loss or seroconversion of HBeAg. Inconsistent histologic responses were reported in the trial.
- In HBeAg negative patients, telbivudine resulted in a statistically significant increase in the proportion of patients with undetectable HBV DNA (NNT=4) and development of viral resistance (NNT=13), but there were no statistically significant differences in histologic or serologic measures of effectiveness.
- The most common adverse event related to telbivudine was elevation of creatine kinase, but there was no statistically significant difference in serious adverse events or withdrawal due to adverse events between telbivudine and lamivudine.
- Based on clinical trial data, a relatively high proportion of patients will develop resistance to telbivudine.
- Telbivudine is more costly than lamivudine, which is listed as a limited coverage benefit for chronic hepatitis B. Based on stated assumptions in the cost-effectiveness model submitted by the manufacturer, the cost-effectiveness of telbivudine is uncertain, especially in HBeAg negative patients.

Decision and Status

- Telbivudine will **not be covered**
- Effective March 27, 2008

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