

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 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.

Gliclazide (Diamicron®) for type 2 diabetes

Understanding the DBC Recommendation and PharmaCare Coverage Decision

Background

- Insulin is a substance produced by the pancreas. It allows glucose (sugar) to pass into the cells and be used for energy. When the body cannot use insulin properly or it does not produce enough insulin, there is a build-up of sugar in the blood. This is called **type 2 diabetes**, which can be a chronic condition.
 - Symptoms may include increased thirst, urinating more often, weight loss, blurry vision, increased hunger or increased tiredness. Some patients have no symptoms.
 - High blood sugar is related to chronic conditions as it causes damage to the blood vessels, heart, nerves, eyes and kidneys.
- Type 2 diabetes is treated with
 - lifestyle changes (diet and exercise)
 - diabetes medications
 - insulin injections
- **Gliclazide** has the brand name **Diamicron®**. There are also several generic products.
 - Gliclazide is part of the class of diabetes medications called oral hypoglycemic agents. It belongs to the group of drugs called **sulfonyureas**.
 - Gliclazide lowers blood sugar by increasing production of insulin by the pancreas.
 - Gliclazide has **limited coverage** for patients who did not respond to, or are unable to take, at least one other drug in the same class (e.g., glyburide or tolbutamide) at adequate doses.

Why was this drug reviewed?

- Drug company request for coverage as a **regular benefit**.

What did the review find?

- Studies show that gliclazide neither works better nor is safer than other drugs in the same class (e.g., glyburide) for the treatment of type 2 diabetes.
- Gliclazide is more costly than other drugs in the same class (e.g., glyburide).

What decision was made?

- Gliclazide will continue to have **limited coverage**. There is no change in criteria for those who can receive limited coverage.

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.
- **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.



Gliclazide (Diamicon®) for type 2 diabetes

Drug Class

- Oral hypoglycemic agent

Available Dosage Forms

- 80mg tablet available as Diamicon® and generics

Sponsor/Requestor

- Servier Canada Inc.

Submission (Request) to PharmaCare

- Request from the manufacturer to modify the current coverage for gliclazide from **limited coverage** with the Special Authority criteria to the **regular benefit** listing. The current Special Authority criteria is:
 - Treatment failure or intolerance to at least one other sulfonylurea drug (e.g., glyburide, tolbutamide) at adequate doses.

Drug Benefit Council (DBC)

Recommendations

- No change to the current limited coverage and Special Authority criteria for gliclazide.

Reasons for the Ministry of Health Services Decision

- A literature search was performed to identify published double-blind, randomized controlled trials (DB RCTs) comparing gliclazide versus other sulfonylureas licensed in Canada for non-insulin dependent type 2 diabetes. Five DB RCTs comparing gliclazide to glyburide (n=4) and glimepiride (n=1) were identified and reviewed.

- There is insufficient evidence that gliclazide provides a statistically significant or clinically important efficacy advantage on surrogate markers, symptoms, morbidity, or mortality compared to other sulfonylureas (e.g., glyburide) for the treatment of type 2 diabetes.
- There is insufficient evidence that gliclazide provides a statistically significant or clinically important safety advantage compared to other sulfonylureas (e.g., glyburide) for the treatment of type 2 diabetes.
- Gliclazide is more costly (has a higher acquisition cost) than glyburide.

Decision and Status

- **Limited coverage.** No change to current Special Authority criteria.
- Effective July 8, 2008

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