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

Oxybutynin controlled-release (Uromax®) for overactive bladder

Understanding the DBC Recommendation and PharmaCare Coverage Decision

Background

- People with overactive bladder have sudden urges to pass urine. It may be hard to stop the urge to pass urine and the urine may leak. This is called incontinence.
- **Oxybutynin** with the brand name **Uromax®** is a controlled-release product. This means that the drug is slowly released from the tablet over a period of 24 hours.
- Oxybutynin is part of the group of drugs called genitourinary smooth muscle relaxants. These drugs control symptoms of overactive bladder by relaxing the bladder muscle. This causes less urge to pass urine and less leakage.

Why was this drug reviewed?

- Drug company request.

What did the review find?

- Studies do not show that oxybutynin controlled-release works better or is safer than other oxybutynin products or other drugs currently being used for overactive bladder.
- Regular oxybutynin is already covered by PharmaCare and is part of the Low Cost Alternative program.

What decision was made?

- Oxybutynin controlled-release will **not be covered.**

Key Term

- **Low Cost Alternative (LCA) Program**: If a number of products (usually generic products) contain the same drug, PharmaCare fully covers those for which B.C. pharmacies have claimed the lowest average cost. For the remaining products, patients pay the difference.

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.

BRITISH COLUMBIA
The Best Place on Earth

Oxybutynin controlled-release (Uromax®) for overactive bladder

Drug Class

- Genitourinary smooth muscle relaxant

Available Dosage Forms

- 10 mg, 15 mg controlled-release (CR) tablets

Sponsor/Requestor

- Purdue Pharma

Submission (Request) to PharmaCare

Health Canada has approved oxybutynin CR for the following indication:

- For the treatment of symptoms of an **overactive bladder**, including urge incontinence, urinary frequency or urgency.

Drug Benefit Council (DBC) Recommendation

- Oxybutynin CR not be listed

Reasons for the Ministry of Health Services Decision

- A literature search was performed to identify published double-blind, randomized controlled trials (DB RCTs) comparing oxybutynin CR to placebo or other drug therapies licensed in Canada for symptomatic treatment of overactive bladder.
- Six DB RCTs comparing oxybutynin CR to oxybutynin immediate-release (IR) were identified and reviewed.
- There is insufficient evidence that oxybutynin CR offers a statistically significant and clinically important efficacy or safety advantage over oxybutynin IR, oxybutynin sustained-release (SR), or alternative anticholinergic drug formulations available in Canada.
- A hypothesis-generating meta-analysis, which included safety data from 5 of 6 DB RCTs, reported a statistically significant reduction in total adverse events with oxybutynin CR (60.2%) compared to oxybutynin IR (70.9%). This corresponds to an absolute risk reduction of 10.7% (95% confidence intervals 3.5% to 17.7%), and a number needed to treat of 9 (95% confidence intervals 6 to 29). However, there was no significant difference in dry mouth or withdrawals due to adverse events between the CR and IR groups.
- The Ministry currently does not provide coverage for other forms of oxybutynin, except oxybutynin IR, which is a regular benefit and part of the Low Cost Alternative program.

Decision and Status

- **Not a benefit**
- Effective February 27, 2008

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