

# 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.

## Ciprofloxacin plus dexamethasone ear drops (Ciprodex®) for ear infection

### Understanding the DBC Recommendation and PharmaCare Coverage Decision

#### Background

- The middle ear is the space behind the eardrum.
- A small tube from the middle ear to the throat allows fluid to drain out of the middle ear. A cold may cause the tube to swell and block fluid drainage. This may lead to a middle ear infection (**otitis media**).
  - Symptoms include earache, fever, yellow fluid draining from the ear (otorrhea) or a plugged feeling.
  - Infection can lead to a hole or tear in the eardrum.
  - Children with frequent middle ear infections may have a plastic tube placed in their ear by a specialist to help drain the fluid from the ear (ear tube or **typanostomy**).
- The outer canal of the ear may also develop an infection. This is called an outer ear infection (**otitis externa**).
  - Symptoms include pain in the ear or yellow fluid draining from the ear.
- The combination of **ciprofloxacin plus dexamethasone** ear drops has the brand name **Ciprodex®**.
  - **Ciprofloxacin** is an antibiotic that kills bacteria.
  - **Dexamethasone** is a steroid medication that decreases swelling.
  - Together they relieve symptoms and help cure middle and outer ear infections.

#### Why was this drug reviewed?

- Drug company request.

#### What did the review find?

- Studies show that ciprofloxacin plus dexamethasone ear drops are better for treating ear infections than some commonly used antibiotics taken by mouth or put into the ear. They may shorten the duration of symptoms and may result in fewer side effects compared to other antibiotics.
- For patients with ear tubes, or a hole or tear in their ear drum(s), these ear drops may be safer than ear drops containing the class of antibiotics called aminoglycosides.
- These ear drops are 2.5 times more costly than other ear drop products containing similar ingredients (antibiotic plus a steroid).

#### What decision was made?

- Ciprofloxacin plus dexamethasone ear drops will have **limited coverage** for 14 days or up to 3 months for the following:
  - middle ear infection with oozing in patients with an ear tube; or
  - outer ear infection for patients with ear tubes, or a hole or tear in their eardrum(s); or
  - failure of, or allergy to, the aminoglycoside class of antibiotic ear drops.

#### 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/pharme](http://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](http://www.health.gov.bc.ca/pharme/formulary).



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## Ciprofloxacin plus dexamethasone ear drops (Ciprodex®) for acute otitis media with otorrhea and otitis externa

### Drug Class

- Antibacterial plus corticosteroid

### Available Dosage Forms

- 0.3 % and 0.1 % otic drops

### Sponsor/Requestor

- Alcon Canada

### Submission (Request) to PharmaCare

- Drug review of ciprofloxacin plus dexamethasone for the following Health Canada-approved indications:
  - Treatment of infections caused by most strains of the designated microorganisms in the specific conditions listed below:
    - 1. Acute otitis media** with otorrhea through tympanostomy tubes in pediatric patients, age six months and older, due to:
      - Aerobic, Gram-positive bacteria: *Streptococcus pneumoniae*, *Staphylococcus aureus*;
      - Aerobic, Gram-negative: *Hemophilus influenzae*, *Moraxella catarrhalis*, *Pseudomonas aeruginosa*.
    - 2. Acute otitis externa** in pediatric, adult and elderly patients, age 1 year and older, due to:
      - Aerobic, Gram-positive: *Staphylococcus aureus*;
      - Aerobic, Gram-negative: *Pseudomonas aeruginosa*.

### Drug Benefit Council (DBC) Recommendation

- Ciprofloxacin plus dexamethasone be listed as a **Limited Coverage** drug with the following Special Authority criteria:
  - Patients with acute otitis media with otorrhea through tympanostomy tubes who require treatment; or
  - Patients with acute otitis externa in the presence of a tympanostomy tube or known perforation of the tympanic membrane; or
  - Failure or intolerance to an aminoglycoside antibiotic.
- Approval period: 14 days supply or treatment period as requested, up to three months.
- No practitioner exemptions.

### 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.

### Reasons for the Ministry of Health Services Decision

- A literature search identified three randomized controlled trials (RCTs) comparing ciprofloxacin plus dexamethasone to topical antibiotics or oral antibiotics in patients with acute otitis media plus tympanostomy tubes. One RCT compared ciprofloxacin plus dexamethasone to ciprofloxacin ophthalmic solution, one RCT compared ciprofloxacin plus dexamethasone to ofloxacin otic solution, and one RCT compared ciprofloxacin plus dexamethasone to oral amoxicillin plus clavulanate.
  - There is sufficient evidence that ciprofloxacin plus dexamethasone provides faster time to resolution of otorrhea, faster time to resolution of clinical symptoms, and less adverse effects when compared to oral amoxicillin plus clavulanate.
- A literature search identified one RCT in patients with acute otitis externa comparing ciprofloxacin plus dexamethasone with neomycin, polymixin B plus hydrocortisone otic suspension.
  - There is marginal benefit to faster resolution of clinical symptoms with ciprofloxacin plus dexamethasone compared to neomycin, polymixin B plus hydrocortisone.
- Ciprofloxacin plus dexamethasone otic suspension provides a treatment option with a potentially lower risk of ototoxicity compared with topical aminoglycoside therapy in patients with tympanostomy tubes or known perforation of the tympanic membrane.
- Ciprofloxacin plus dexamethasone otic suspension is approximately 2.5 times more costly than other topical otic antibiotic plus corticosteroid combination products.

### Decision and Status

- **Limited coverage**, as per the Special Authority criteria set-forth in the DBC recommendation.
- Effective January 16, 2009