

Drug Coverage Decision for B.C. PharmaCare

About PharmaCare

B.C. PharmaCare is a government-funded drug plan. It helps British Columbians with the cost of eligible prescription drugs and specific medical supplies.

Details of Drug Reviewed

Drug	Ciprofloxacin-dexamethasone
Brand Name	Ciprodex® and generics
Dosage Form(s)	0.3% w/v ciprofloxacin / 0.1% w/v dexamethasone otic suspension
Manufacturer	Novartis Pharmaceuticals Canada Inc. Taro Pharmaceuticals Inc.
Submission Type	Modification of Criteria
Use Reviewed	<p>Treatment of infections caused by most strains of the designated microorganisms in the specific conditions listed below:</p> <ol style="list-style-type: none"> Acute otitis media with otorrhea through tympanostomy tubes in pediatric patients, age six months and older, due to: <ul style="list-style-type: none"> Aerobic, Gram-positive bacteria: <i>Streptococcus pneumonia</i>, <i>Staphylococcus aureus</i>; Aerobic, Gram-negative: <i>Hemophilus influenzae</i>, <i>Moraxella catarrhalis</i>, <i>Pseudomonas aeruginosa</i>. Acute otitis externa in adult and pediatric patients age 1 year and older, due to: <ul style="list-style-type: none"> Aerobic, Gram-positive: <i>Staphylococcus aureus</i>; Aerobic, Gram-negative: <i>Pseudomonas aeruginosa</i>.
Common Drug Review (CDR)	<p>CDR recommended: Do Not Reimburse when first reviewed on November 17, 2004. On September 19, 2007, the CDR changed their recommendation to Reimburse after the discontinuation of ciprofloxacin/hydrocortisone (Cipro HC®) otic suspension in Canada. Visit the CDR website for more details:</p> <p>www.cadth.ca/sites/default/files/cdr/complete/cdr_complete_Ciprodex_feb24-06.pdf</p> <p>www.cadth.ca/sites/default/files/cdr/complete/cdr_complete_Ciprodex_October-18-2007.pdf</p>

Drug Benefit Council (DBC)	<p>The DBC met on February 18, 2008, and considered various inputs including: the recommendations from the CDR.</p> <p>The DBC recommended ciprofloxacin/dexamethasone otic suspension be listed as a Limited Coverage drug with the following Special Authority criteria:</p> <p>Patients with acute otitis media with otorrhea through tympanostomy tubes who require treatment and in patients with acute otitis externa in the presence of a tympanostomy tube or known perforation of the tympanic membrane.</p> <p>OR</p> <p>Failure or intolerance to an aminoglycoside antibiotic.</p> <p>Approval period: 14 days supply or treatment period as requested up to three months.</p> <p>No exemption for specialists.</p>
Drug Coverage Decision	Regular Benefit, this supercedes the Limited Coverage Benefit decision from January 16, 2009.
Date	February 6, 2021
Reason(s)	<p>Drug coverage decision is consistent with the 2007 CDEC recommendation.</p> <ul style="list-style-type: none"> • Ciprofloxacin-dexamethasone otic suspension is considered a first line therapy for the treatment of acute otitis externa and acute otitis media with otorrhea through tympanostomy tubes due to its antimicrobial spectrum, anti-inflammatory effects, and lack of potential ototoxicity. • The alternative medications to ciprofloxacin-dexamethasone are now either discontinued (e.g. gentamycin), of limited availability (e.g. Sofracort), and are not intended for use in patients with perforated eardrum or tympanostomy tubes due to potential ototoxicity. • Changing the benefit status from Limited Coverage to Regular Benefit facilitates timely access to this first-line therapy, given the limited availability of alternatives.
Other Information	<p>Ciprofloxacin-dexamethasone otic suspension drug decision summary from January 16, 2009: www2.gov.bc.ca/assets/gov/health/health-drug-coverage/pharmacare/decisions/dds-0001.pdf</p>

The Drug Review Process in B.C.

A manufacturer submits a request to the Ministry of Health (Ministry).

An independent group called the [Drug Benefit Council \(DBC\)](#) gives advice to the Ministry. The DBC looks at:

- whether the drug is safe and effective
- advice from a national group called the [Common Drug Review \(CDR\)](#)
- what the drug costs and whether it is a good value for the people of B.C.
- ethical considerations involved with covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes PharmaCare coverage decisions by taking into account:

- the existing PharmaCare policies, programs and resources
- the evidence-informed advice of the DBC
- the drugs already covered by PharmaCare that are used to treat similar medical conditions
- the overall cost of covering the drug

Visit [The Drug Review Process in B.C. - Overview](#) and [Ministry of Health - PharmaCare](#) for more information.

This document is intended for information only.

It does not take the place of advice from a physician or other qualified health care provider.

Canadian Agency for
Drugs and Technologies
in Health

Agence canadienne
des médicaments et des
technologies de la santé

CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

CIPROFLOXACIN HCL and DEXAMETHASONE OTIC SUSPENSION (Ciprodex® – Alcon Canada)

Description:

Ciprodex® is a combination of ciprofloxacin HCl and dexamethasone that is indicated for the local treatment of acute otitis media with otorrhea through tympanostomy tubes in pediatric patients aged six months and older and for acute otitis externa in pediatric and adult patients aged one year and older.

The review of ciprofloxacin HCl/dexamethasone (Ciprodex®) by the Common Drug Review was in response to a Request for Advice from the Advisory Committee on Pharmaceuticals which questioned if the CEDAC recommendation of January 26, 2005 that ciprofloxacin HCl/dexamethasone (Ciprodex®) not be listed, should be changed in light of the recent withdrawal from the market of otic ciprofloxacin HCl/hydrocortisone (Cipro HC®).

Recommendation:

The Canadian Expert Drug Advisory Committee (CEDAC) recommends that ciprofloxacin HCl/dexamethasone (Ciprodex®) otic suspension be listed in patients with acute otitis media with otorrhea through tympanostomy tubes who require treatment and in patients with acute otitis externa in the presence of a tympanostomy tube or known perforation of the tympanic membrane.

Reasons for the Recommendation:

1. For patients with otitis externa, one randomized trial compared topical otic ciprofloxacin HCl/dexamethasone with neomycin, polymixin B and hydrocortisone otic suspension and found a slight advantage in favor of topical ciprofloxacin HCl/dexamethasone in symptoms on days three and eighteen, but not on day eight.
2. For patients with otitis media with tympanostomy tubes, available studies compare ciprofloxacin HCl/dexamethasone otic suspension with ciprofloxacin ophthalmic solution (Ciloxan®) and with ofloxacin otic solution. Compared to ciprofloxacin ophthalmic solution, the clinical cure rate was significantly higher with ciprofloxacin HCl/dexamethasone at day 3, but not at day 8 or 14. In a second trial, topical ciprofloxacin HCl/dexamethasone resulted in a slightly greater improvement in symptoms compared to ofloxacin otic solution, although the clinical importance of these differences is unclear.
3. Ciprofloxacin HCl/dexamethasone provides a treatment option with low potential for ototoxicity in patients with tympanostomy tubes or known perforation of the tympanic membrane.

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Summary of Committee Considerations:

The Committee considered a systematic review of three randomized controlled trials (RCTs) of ciprofloxacin HCl/dexamethasone in patients with acute otitis media and one RCT in patients with acute otitis externa.

Ciprofloxacin HCl/dexamethasone (Ciprodex®) costs \$25.20 for a 7.5 mL bottle which is more expensive than other topical otic antibiotic/corticosteroid combination products: framycetin/gramicidin/dexamethasone cost \$7.84 for 8 mL, polymixin/neomycin/hydrocortisone costs \$10.14 for 10 mL and gentamicin/betamethasone costs \$8.97 for 7.5 mL.

Of Note:

1. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.
2. The Committee considered data on the ototoxicity of various agents in patients with otitis media with perforation of the tympanic membrane or tympanostomy tubes. While the Committee recognizes the place in therapy of ciprofloxacin HCl/dexamethasone in selected patients with non-intact tympanic membranes other, less costly management options are available for the treatment of acute otitis media and otitis externa.

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