

Clinical Pharmacy Program Guidelines for Ciprodex

Program	Prior Authorization
Medication	Ciprodex (ciprofloxacin/dexamethasone otic suspension)
Issue Date	12/2009
Pharmacy and Therapeutics Approval Date	3/2018
Effective Date	5/2018

1. Background:

FDA Approved Indications

1. Acute Otitis Media (AOM)

Ciprodex Otic is indicated for the treatment of acute otitis media in pediatric patients (age 6 months and older) with tympanostomy tubes due to *S. aureus*, *S. pneumoniae*, *H. influenzae*, *M. catarrhalis*, and *P. aeruginosa*.

2. Acute Otitis Externa (AOE)

Ciprodex Otic is indicated for the treatment of acute otitis externa in pediatric (age 6 months and older), adult, and elderly patients due to *S. aureus* and *P. aeruginosa*.

2. Coverage Criteria:

<p>A. <u>Authorization</u></p> <p>1. <u>One</u> of the following:</p> <p style="margin-left: 40px;">a. The patient has AOM or AOE with a perforated tympanic membrane or tympanostomy tubes.</p> <p style="text-align: center; margin: 10px 0;">-OR-</p> <p style="margin-left: 40px;">b. The patient has had an inadequate response, intolerance or contraindication to at least one preferred alternative.</p> <p>Authorization will be issued for 1 month.</p>

3. References:

1. Ciprodex® Otic Prescribing Information. Alcon, Inc., December 2015.
2. Facts and Comparisons 4.0, 2012.
3. Clinical Pharmacology Gold Standard 2012.
4. Ruohola A, Meurman O, Nikkari S. Microbiology of acute otitis media in children with tympanostomy tubes: prevalences of bacteria and viruses. Clin Infect Dis. 2006; 43(11):1417-22.
5. Rosenfeld RM, Brown L, Cannon CR, et al for the American Academy of Otolaryngology--Head and Neck Surgery Foundation. Clinical practice guideline: acute otitis externa. Otolaryngol Head Neck Surg. 2006; 134(4 Suppl):S4-23.
6. Sander R. Otitis externa: a practice guide to treatment and prevention. Am Fam Physician. 2001; 63:927-936,941-942.
7. Rosenfeld RM, Singer M, Wasserman JM, et al. Systematic review of topical antimicrobial therapy for acute otitis externa. Otolaryngol Head Neck Surg. 2006; 134(suppl):S24-48.
8. Lieberthal AS, Ganiats TG, Cox EO, et al for the American Academy of Pediatrics and the American Academy of Family Physicians. Clinical Practice Guidelines: Diagnosis and Management of Acute Otitis Media. Pediatrics. 2004; 113(5):1451-1465.

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Change Control	
Date	Change
12/2009	Criteria taken from previously approved AmeriChoice policy. Policy reformatted.
12/2010	Annual Review
9/2011	Annual Review
9/2012	Annual Review
12/2015	Annual Review
11/2016	Annual review, updated policy template
3/2017	Updated template. No changes to clinical criteria.
3/2018	Annual Review. Updated references. Removed “initial” from authorization header since there is only one section of the policy.