

## **Clinical Policy: Ciprofloxacin/Dexamethasone (Ciprodex)**

Reference Number: HIM.PA.120

Effective Date: 12.01.17

Last Review Date: 11.18

Line of Business: HIM

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Ciprofloxacin and dexamethasone (Ciprodex<sup>®</sup>) otic suspension is a combination of ciprofloxacin, a fluoroquinolone antibacterial and dexamethasone, a corticosteroid.

### **FDA Approved Indication(s)**

Ciprodex is indicated for the treatment of infections caused by susceptible isolates of the designated microorganisms in the specific conditions listed below:

- Acute otitis media in pediatric patients (age 6 months and older) with tympanostomy tubes due to *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, and *Pseudomonas aeruginosa*.
- Acute otitis externa in pediatric (age 6 months and older), adult and elderly patients due to *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

### **Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Ciprodex is **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

##### **A. Acute Otitis (must meet all):**

1. Diagnosis of acute otitis;
2. Age  $\geq$  6 months;
3. Member meets one of the following (a or b):
  - a. Recent (within the last 3 months) use of an oral antibiotic indicated for otitis media and presence of tympanostomy tubes;
  - b. Diagnosis of otitis externa;
4. Dose does not exceed 7.5 mL (1 bottle).

**Approval duration: 14 days (1 bottle)**

##### **B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

**II. Continued Therapy**

**A. Acute Otitis** (must meet all):

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

**Approval duration: Not applicable**

**Other diagnoses/indications** (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 12 months (whichever is less);** or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PHAR.21 for health insurance marketplace.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
amoxicillin (Amoxil <sup>®</sup> )	80 to 90 mg/kg/day PO in two divided doses	90 mg/kg/day
amoxicillin-clavulanate (Augmentin <sup>®</sup> )	90 mg/kg/day amoxicillin and 6.4 mg/kg/day clavulanate PO in two divided doses	90 mg/kg/day amoxicillin and 6.4 mg/kg/day

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

*Note: Choice of antibiotic therapy includes but is not limited to the agents listed here.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s):
  - History of hypersensitivity to ciprofloxacin, to other quinolones, or to any of the components in Ciprodex
  - Use in viral infections of the external canal including herpes simplex infections and fungal otic infections
- Boxed warning(s): none reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Acute otitis media, acute otitis externa	Instill 4 drops into the affected ear BID for 7 days	8 drops/ear (max: 7 days)

**VI. Product Availability**

Otic suspension: ciprofloxacin 0.3% and dexamethasone 0.1% (7.5 mL)

**VII. References**

1. Ciprodex Prescribing Information. Fort Worth, TX: Alcon Laboratories, Inc.; December 2015. Available at: [www.ciprodex.com](http://www.ciprodex.com). Accessed August 14, 2018.
2. American Academy of Pediatrics Subcommittee on Management of Acute Otitis Media. Diagnosis and management of acute otitis media. *Pediatrics*. 2013;131:e964-e999.
3. Schaefer P, Baugh R. Acute otitis externa: An update. *Am Fam Physician*. 2012; 86(11):1055-1061.
4. Sander R. Otitis externa: A practical guide to treatment and prevention. *Am Fam Physician* 2001;63:927-36, 941-2.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.31.17	11.17
4Q 2018 annual review: no significant changes; references reviewed and updated.	08.14.18	11.18

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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