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®) 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® 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 ≥ 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.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
amoxicillin (Amoxil®)	80 to 90 mg/kg/day PO in two divided doses	90 mg/kg/day
amoxicillin-clavulanate (Augmentin®)	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® (generic) when the drug is available by brand name only and generic (Brand name®) 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. 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

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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