Clinical Policy: Ciprofloxacin/Dexamethasone (Ciprodex)

Reference Number: CP.PMN.248
Effective Date: 12.01.20
Last Review Date: 11.22
Line of Business: HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Ciprofloxacin/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 otitis;
2. Age ≥ 6 months;
3. For brand Ciprodex requests, member must use generic ciprofloxacin/dexamethasone otic suspension, unless contraindicated or clinically significant adverse effects are experienced (i.e., contraindication to excipients);
4. Member meets one of the following (a or b):
   a. Diagnosis of otitis externa;
   b. Diagnosis of otitis media with both of the following (i and ii):
      i. Recent (within the last 3 months) use of an oral antibiotic indicated for otitis media (*see Appendix B*)
      ii. Presence of tympanostomy tubes;
5. Dose does not exceed 7.5 mL (1 bottle).

Approval duration: 14 days (1 bottle)

B. Other diagnoses/indications (must meet 1 or 2):
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid.

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.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid, or evidence of coverage documents.

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®)	**Acute Otitis Media** 80 to 90 mg/kg/day PO in two divided doses	90 mg/kg/day
amoxicillin-clavulanate (Augmentin®)	**Acute Otitis Media** 90 mg/kg/day amoxicillin and 6.4 mg/kg/day clavulanate PO in two divided doses	90 mg/kg/day of amoxicillin component
cefdinir	**Acute Otitis Media** 14 mg/kg PO per day in 1 or 2 doses	600 mg/day
cefuroxime	**Acute Otitis Media** 30 mg/kg PO per day in 2 divided doses	1,000 mg/day
cefpodoxime	**Acute Otitis Media** 10 mg/kg PO per day in 2 divided doses	400 mg/day
ceftriaxone	**Acute Otitis Media** 50 mg IM or IV per day for 1 or 3 days	4 g/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 (7.5 mL): ciprofloxacin 0.3% and dexamethasone 0.1%

VII. References

1. Ciprodex Prescribing Information. Fort Worth, TX: Alcon Laboratories, Inc.; November 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021537s018lbl.pdf. Accessed July 5, 2022.

2. American Academy of Pediatrics Subcommittee on Management of Acute Otitis Media. Diagnosis and management of acute otitis media. Reaffirmed 2019; 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.
5. Rosenfeld RM, Schwartz SR, Cannon CR, et al. Clinical practice guideline: acute otitis externa. Otolaryngology-Head and Neck Surgery. 2014;150(1S):S1-S24.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created (adopted from HIM.PA.120, policy to retire); added Medicaid line of business; references reviewed and updated.	08.21.20	11.20
4Q 2021 annual review: added that member must use generic formulation; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	08.11.21	11.21
4Q 2022 annual review: no significant changes; clarified that generic requirement applies to brand Ciprodex requests; references reviewed and updated. Template changes applied to other diagnoses/indications.	07.05.22	11.22

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.