Clinical Policy: Otic Agents: Antibacterial and Antibacterial/Steroid Combinations

Reference Number: OH.PHAR.PPA.79
Effective Date: 01/01/2020 Revision Log
Last Review Date:
Line of Business: Medicaid

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

Description

OTIC AGENTS: ANTIBACTERIAL – STERIOD COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CIPRO HC® suspension (ciprofloxacin with hydrocortisone) CIPRODEX® suspension (ciprofloxacin with dexamethasone) NEOMYCIN-POLYMYXIN B WITH HYDROCORTISONE solution (generic of Cortisporin® solution) NEOMYCIN-POLYMYXIN B WITH HYDROCORTISONE suspension (generic of Cortisporin® suspension)	COLY-MYCIN-S® suspension (neomycin and colistin with hydrocortisone) CORTISPORIN-TC® suspension (neomycin and colistin with hydrocortisone) OTOVEL® (ciprofloxacin with fluocinolone)

OTIC AGENTS: ANTIBACTERIAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
OFLOXACIN drops (generic of Floxin Otic®)	CIPROFLOXACIN (generic of Cetraxal®)

FDA approved indication(s)

Ciprodex is indicated for:

- Treatment of acute otitis media due to susceptible organisms in children with tympanostomy tubes aged 6 months and older.
- Treatment of acute otitis externa due to susceptible organisms in adults and children 6 months of age and older.

Ciprofloxacin is indicated for:

- Treatment of acute otitis externa due to susceptible isolates of *Pseudomonas aeruginosa* or *Staphylococcus aureus* in children, adolescents, and adults.

Cipro HC is indicated for:

- Treatment of acute otitis externa due to susceptible organisms in adults and children 1 year of age and older.

Coly-Mycin-S is indicated for:

- Treatment of superficial bacterial infections of the external auditory canal (i.e., otitis externa) caused by susceptible organisms, and for the treatment of infections of mastoidectomy and fenestration cavities caused by susceptible organisms in children, adolescents, and adults.

Cortisporin-TC is indicated for:

- Treatment of superficial bacterial infections of the external auditory canal (i.e., otitis externa) caused by susceptible organisms, and for the treatment of infections of mastoidectomy and fenestration cavities caused by susceptible organisms in children, adolescents, and adults.

Neomycin-Polymyxin B with Hydrocortisone is indicated for:

- Treatment of superficial bacterial infections of the external auditory canal (i.e., otitis externa) caused by susceptible organisms, and for the treatment of infections of mastoidectomy and fenestration cavities caused by susceptible organisms in infants, children, adolescents, and adults.

Ofloxacin is indicated for:

- For acute otitis media in children with tympanostomy tubes due to *H. influenzae* (beta-lactamase negative), *H. influenzae* (beta-lactamase positive), *M. catarrhalis*, *P. aeruginosa*, *S. aureus*, or *S. pneumonia.*
- For chronic suppurative otitis media in adults and adolescents with perforated tympanic membranes due to *P. mirabilis*, *P. aeruginosa*, or *S. aureus.* in adults and children 12 years of age and older.
- Treatment of otitis externa due to *E. coli*, *P. aeruginosa*, and *S. aureus* in adults and adolescents.

Otovel is indicated for:

- Treatment of acute otitis media with tympanostomy tubes (AOMT) due to susceptible organisms in infants and children 6 months of age and older.

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 Buckeye Health Plan, an affiliate of Centene Corporation® that Otic Agents: Antibacterial and Antibacterial/Steroid Combinations are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias;
2. Member must meet labeled age requirements for the medication;
3. Failure of ≥ 7 days of one preferred medication, unless member meets one of the following (a, b, c, or d):
   a. Allergy to medications not requiring prior approval;
   b. Contraindication to or drug interaction with medications not requiring prior approval;
   c. History of unacceptable/toxic side effects to medications not requiring prior approval;

d. Culture and sensitivity (C&S) report for the current infection shows resistance of the organism to preferred medications, unless provider submits documentation that obtaining a C&S report is not feasible.

Approval Duration: 10 days

II. 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 policy - CP.PMN.53 or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation Key

AOMT: Acute otitis media in children with tympanostomy tubes
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
Ciprodex® (ciprofloxacin with dexamethasone)	Instill 4 drops into affected ear BID for 7 days	8 drops/day to affected ear(s)
Cipro HC® (ciprofloxacin with hydrocortisone)	Instill 3 drops into affected ear(s) BID for 7 days	6 drops/day to affected ear(s)
Neomycin-Polymyxin B with hydrocortisone (Cortisporin®)	Instill 4 drops into affected ear(s) 3 to 4 times daily for no longer than 10 days	N/A
Ofloxacin (Floxin Otic®)	Acute otitis media in children with tympanostomy tubes: Instill 5 drops into affected ear BID for 10 days Chronic suppurative otitis media in adults and adolescents with perforated tympanic membranes: Instill 10 drops into affected ear BID for 14 days Otitis externa: Adults and adolescents: Instill 10 drops into affected ear QD for 7 days Infants and children aged 6 months to 13 years: Instill 5 drops into affected ear QD for 7 days	See each indication

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.

Appendix C: Contraindications/Boxed warnings

- Contraindications(s):
  - Aminoglycoside or neomycin hypersensitivity (Cortisporin TC, Coly-Mycin S, Neomycin-Polymyxin B-hydrocortisone)
  - External auditory canal viral infection, such as varicella-zoster or other herpes infection (Cortisporin TC, Coly-Mycin S, Cipro HC, Ciprodex, Neomycin-Polymyxin B-hydrocortisone, Otovel)
  - Corticosteroid hypersensitivity (Ciprodex, Cipro HC, Cortisporin, Coly-Mycin S, Cortisporin TC, Otovel)
  - Quinolone hypersensitivity (Cipro HC, Ciprodex, ofloxacin, Otovel, ciprofloxacin)
  - Tympanic membrane perforation (Cipro HC, Neomycin-Polymyxin B-hydrocortisone)
  - Fungal infection (Neomycin-Polymyxin B-hydrocortisone)
  - Sulfite hypersensitivity (Neomycin-Polymyxin B-hydrocortisone)
  - Fluocinolone acetonide hypersensitivity (Otovel)
- Boxed warning(s): none reported

IV. Dosage and Administration

Drug	Dosing Regimen	Maximum Dose
Ciprofloxacin (Cetraxal®)	0.5mg (one 0.25mL single-use container) in the affected ear(s) every 12 hours for 7 days	1 mg/ear/day
Coly-Mycin-S® (neomycin and colistin with hydrocortisone)	Adults: Instill 5 drops into affected ear(s) 3 to 4 times daily. Limit treatment to 10 days. Children and Adolescents: Instill 4 drops into affected ear(s) 3 to 4 times daily. Limit treatment to 10 days.	10 days of dosing per treatment course
Cortisporin-TC® (neomycin and colistin with hydrocortisone)	Adults: Instill 5 drops into affected ear(s) 3 to 4 times daily. Limit treatment to 10 days. Children and Adolescents: Instill 4 drops into affected ear(s) 3 to 4 times daily. Limit treatment to 10 days.	10 days of dosing per treatment course
Otovel® (ciprofloxacin with fluocinolone)	Instill 0.25 mL (one single-dose vial) into the affected ear canal BID (approximately every 12 hours) for 7 days	0.5mL/ear/day

For preferred agents please see Appendix B.

V. Product Availability

Drug	Availability
Ciprodex® (ciprofloxacin with dexamethasone)	Otic suspension: ciprofloxacin 0.3%, dexamethasone 0.1%
Ciprofloxacin (Cetraxal®)	Otic solution: 0.2%
Cipro HC® (ciprofloxacin with hydrocortisone)	Otic suspension: ciprofloxacin 0.2%, hydrocortisone 1%
Coly-Mycin-S® (neomycin and colistin with hydrocortisone)	Otic suspension: neomycin 3.3mg/1mL, colistin 3mg/1mL, hydrocortisone 1%
Cortisporin-TC® (neomycin and colistin with hydrocortisone)	Otic suspension: neomycin 3.3mg/1mL, colistin 3mg/1mL, hydrocortisone 1%
Neomycin-Polymyxin B with hydrocortisone (Cortisporin®)	Otic solution: neomycin 3.5mg/1mL, polymyxin B 10,000U/1mL, hydrocortisone 1%
Ofloxacin (Floxin Otic®)	Otic solution: 0.3%
Otovel® (ciprofloxacin with fluocinolone)	Otic solution: ciprofloxacin 0.3%, fluocinolone acetonide 0.025%

VI. References

Refer to package inserts.

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created	10/19	

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.