

Clinical Pharmacy Program Guidelines for Ciprodex

Program	Prior Authorization
Medication	Ciprodex (ciprofloxacin/dexamethasone otic suspension)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	12/2009
Pharmacy and Therapeutics Approval Date	3/2020
Effective Date	5/2020

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 *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, and *Pseudomonas 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 *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

2. Coverage Criteria:

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

Authorization will be issued for 1 month.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Ciprodex[®] Otic Prescribing Information. Novartis Pharmaceuticals Corporation; East Hanover, NJ. February 2019.
2. 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. 2014; 150(1 Suppl):S1-24.
3. Sander R. Otitis externa: a practice guide to treatment and prevention. Am Fam Physician. 2012; 86(11):1055-61
4. Lieberthal AS, Carroll AE, Chonmaitree T, et al. The Diagnosis and Management of Acute Otitis Media. Pediatrics. 2013; 131 (3) e964-99.

Program	Prior Authorization- Ciprodex (ciprofloxacin/dexamethasone otic suspension)
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.
3/2019	Revised policy flow to align with DX2RX. Updated references.
3/2020	Annual review, updated references.

