

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

*FHK- Florida Healthy Kids

Non-Preferred Fluoroquinolone – Fluoroquinolone Combination Otic Agents

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Comment	Quantity Limit
ciprofloxacin otic	Preferred	May be subject to quantity limit
ofloxacin otic		
Cetraxal otic	Non-Preferred	
Cipro HC otic		
Ciprodex otic		
Otovel otic		

APPROVAL CRITERIA

Requests for brand fluoroquinolone otic agents (Cetraxal, Ciprodex, Cipro HC, or Otovel) may be approved for the following criteria:

- I. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one generic (such as but not limited to generic ofloxacin) or generic combination agent (such as but not limited to, a generic otic fluoroquinolone, or a generic otic or ophthalmic steroid, or a generic otic aminoglycoside); **OR**
- II. The generic agent or combination agent is not FDA-approved and does not have an accepted off-label use per the off-label policy for the prescribed indication and the requested non-preferred agent does; **OR**
- III. The generic agent or combination agent is not acceptable due to concomitant clinical conditions, such as but not limited to the following:
 - A. Known hypersensitivity to any ingredient which is not also present or associated with the requested brand fluoroquinolone or fluoroquinolone combination otic agent; **OR**
 - B. Individual has a perforated tympanic membrane and the preferred generic agent or combination agent is contraindicated or not recommended for use within this population; **OR**
 - C. The generic agent or combination agent does not have antimicrobial activity against susceptible bacterial strains (*Staphylococcus aureus*, *Streptococcus*

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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pneumoniae, Haemophilus influenzae, Moraxella catarrhalis, Proteus mirabilis, or Pseudomonas aeruginosa).

OR

- IV. Ciprodex (ciprofloxacin-dexamethasone) or Otovel (ciprofloxacin-fluocinolone) may be approved if requested for the treatment of acute otitis media and ofloxacin otic is unavailable (for example, on manufacturer backorder).

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.

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