

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X

Non-Preferred Ciprofloxacin – Ciprofloxacin Combination Otic Agents

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

Medications	Comment	Quantity Limit
ciprofloxacin otic with or without a separate otic/ophthalmic corticosteroid	Preferred	May be subject to quantity limit
Floxin (ofloxacin) otic with or without a separate otic/ophthalmic corticosteroid		
neomycin/polymyxin B/hydrocortisone		
Cetraxal otic – brand and generic	Non-Preferred	
Cipro HC otic		
Ciprodex otic – brand and generic		
Otovel otic – brand and generic		

APPROVAL CRITERIA

Requests for Cetraxal otic – brand and generic, Ciprodex otic – brand and generic, Cipro HC otic, or Otovel otic – brand and generic may be approved if the following criteria are met:

- 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 preferred agent or combination therapy/agent;

Preferred agents or combination therapy/agents: Otic aminoglycoside (such as neomycin/polymyxin B/hydrocortisone); otic fluoroquinolone [ciprofloxacin, Floxin (ofloxacin)] with or without a separate otic/ophthalmic corticosteroid (such as hydrocortisone, dexamethasone)

OR

- II. The preferred agent or therapy/agents are not FDA-approved and does not have an accepted off-label use per the off-label policy for the prescribed indication and the requested ciprofloxacin otic or ciprofloxacin combination otic agent does;

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OR

- III. The preferred agent or therapy/agents are 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 in the requested ciprofloxacin otic or ciprofloxacin combination otic agent; **OR**
 - B. Individual's age; **OR**
 - C. Individual has a perforated tympanic membrane and the preferred agent or therapy/agents are contraindicated or not recommended for use within this population; **OR**
 - D. The preferred agent or therapy/agents do not have antimicrobial activity against susceptible bacterial strains (*Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Proteus mirabilis*, or *Pseudomonas aeruginosa*).

OR

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

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: March 11, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Jackson MA, Schutze GE, American Academy of Pediatrics Committee on Infectious Diseases. The Use of Systemic and Topical Fluoroquinolones. *Pediatrics*. 2016; 138(5):e20162706. Available from: <http://pediatrics.aappublications.org/content/138/5/e20162706>. Accessed on: March 11, 2020.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
6. Rosenfeld RM, Schwartz SR, Cannon CR, et al. The American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) Clinical Practice Guideline: Acute Otitis Externa. *Otolaryngol Head Neck Surg*. 2014; 150(1S): S1-S24. Available from: http://oto.sagepub.com/content/150/1_suppl/S1.full.pdf+html. Accessed on: March 11, 2020.
7. Rosenfeld RM, Schwartz SR, Pynnonen MA, et al. The American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) Clinical Practice Guideline: Tympanostomy Tubes in Children. *Otolaryngol Head Neck Surg*. 2013; 149(1 Suppl):S1-S35. Available from: <http://www.entnet.org/content/clinical-practice-guidelines>. Accessed on: March 11, 2020.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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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