

**Indiana Medicaid Therapeutics Committee**  
**Therapeutic Class Review Summary**

**Therapeutic Class:**

Otic Antibiotics

**Overview:**

The otic antibiotics discussed in this review include Cetraxal<sup>®</sup>, Ciprodex<sup>®</sup>, Cipro<sup>®</sup> HC, Cortisporin<sup>®</sup>, and Floxin<sup>®</sup>. These products are generally used to treat acute otitis externa, a bacterial infection of the external auditory canal; however, Ciprodex<sup>®</sup> and Floxin<sup>®</sup> have additional indications for acute otitis media in patients with tympanostomy tubes. Floxin<sup>®</sup> is the only agent in this class approved for chronic suppurative otitis media.

According to the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) guidelines, 65% to 90% of patients have clinical resolution of otitis externa within 7 to 10 days regardless of the topical agent used. Products containing various combinations of neomycin, polymyxin, and hydrocortisone (e.g., Cortisporin<sup>®</sup>) have been used for many years and have comparable efficacy. Additionally, the fluoroquinolones (ofloxacin and ciprofloxacin), which are broad-spectrum antibiotics with a favorable safety profile, are alternative treatment options. The AAO-HNSF guidelines also indicate topical agents should be recommended as initial therapy for diffused uncomplicated acute otitis externa in children two years of age and older.

Ciprofloxacin was recently approved as the single agent Cetraxal<sup>®</sup>, while ciprofloxacin in combination with hydrocortisone is marketed as Cipro<sup>®</sup> HC and the combination of ciprofloxacin and dexamethasone marketed as Ciprodex<sup>®</sup>. Additionally, ofloxacin is available as the single agent Floxin<sup>®</sup> Otic, which was the first topical agent indicated for both otitis externa and otitis media in children with tympanostomy tubes. It was also approved for chronic suppurative and acute otitis media for patients one year of age and older. Ciprodex<sup>®</sup> is indicated for both acute otitis externa and acute otitis media for patients 6 months of age and older; however, Cipro<sup>®</sup> HC and Cetraxal<sup>®</sup> do not have the additional otitis media indication and are for acute otitis externa only. Though the overall incidence of adverse reactions is low with use of the otic antibiotics, pruritis and site reactions have been most commonly reported. Other potential adverse events include rash, discomfort, otalgia, dizziness, vertigo, superinfection, and reduced hearing. Quinolones with added corticosteroids, such as Ciprodex<sup>®</sup> and Cipro<sup>®</sup> HC, appear to provide faster relief of symptoms.

<b>Generic Name</b>	<b>Trade Name</b>	<b>Dosage Form</b>	<b>Manufacturer</b>	<b>Generic</b>
Ciprofloxacin	Cetraxal <sup>®</sup>	Solution	WraSer Pharmaceuticals	N
Ciprofloxacin & Dexamethasone	Ciprodex <sup>®</sup> Otic	Suspension	Alcon	N
Ciprofloxacin & Hydrocortisone	Cipro <sup>®</sup> HC Otic	Suspension	Akorn	N
Neomycin, Polymyxin, Hydrocortisone	Cortisporin <sup>®</sup>	Solution, Suspension	Various	Y
Ofloxacin	Floxin <sup>®</sup> Otic	Solution	Daiichi	Y

**Summary:**

For many years, the products of choice for acute otitis externa have been combination products containing neomycin and polymyxin B sulfate. When pain and inflammation are present, these agents combined with hydrocortisone are the preferred choice. The newest alternatives in the arsenal of ototopical agents are the quinolones, which have no known ototoxic effects. Because these products have comparable efficacy, selection of agents for the preferred drug list should take the spectrum of coverage, safety, and cost into consideration. Cortisporin<sup>®</sup> and Floxin<sup>®</sup> Otic are available generically and could be included on the PDL; however, at least one of the quinolones should be included for treatment of acute otitis media.