



Therapeutic Class ReviewSM

Anti-infectives - Otic Products - Ciprodex[®] – Cipro HC[®]

July 2007

Executive Summary:

- Ciprodex was last reviewed by the P and T Committee in March 2005. At that time, the Committee determined that Ciprodex offered no additional clinical benefit for its extra cost over other otic or oral formulary/preferred options for empiric treatment of acute otitis externa (AOE), acute otitis media (AOM) and acute otitis media with otorrhea through tympanostomy tubes (AOMT).
- In the last three years, market changes have made Ciprodex cost-neutral with Cipro HC.
- Pediatricians indicate Ciprodex is a practical option for treatment of AOMT because of:
 - Convenience of otic administration in children, instead of oral antibiotics.
 - Sterile formulation of Ciprodex prevents potential for secondary infections when administered in children with tympanostomy tubes via otic route.

Decision

Ciprofloxacin, 0.3%/dexamethasone, 0.1% (Ciprodex) is a formulary/preferred product because:

- Market changes have made Ciprodex equal in value to Cipro HC.
- This product is a practical and convenient option for otic administration in children with AOMT (instead of oral antibiotics).

Appendix 1: Cipro HC and CiproDex Product Information

Drug Product	Date of FDA Approval	Patent Expiration	FDA Approved Indication(s)	Dose Route
Ciprofloxacin 0.3%, dexamethasone 0.1% (CiproDex) otic suspension – 7.5ml	07/18/03	Feb 2008 – Aug 2020	Acute otitis media (AOM) in pediatric patients (≥6 months old) with tympanostomy tubes due to <i>Staphylococcus aureus</i> , <i>Streptococcus pneumoniae</i> , <i>Haemophilus influenzae</i> , <i>Moraxella catarrhalis</i> , and <i>Pseudomonas aeruginosa</i> ; Acute otitis externa (AOE) in patients (≥6 months old), adult and elderly patients due to <i>Staphylococcus aureus</i> and <i>Pseudomonas aeruginosa</i> .	Otitis media, in patients with tympanostomy tubes: 6 moths and older, 4 drops into the affected ear twice a day for 7 days Otitis externa, acute: 4 drops into the affected ear twice a day for 7 days.
Ciprofloxacin 0.2%, hydrocortisone 1% (Cipro HC) otic suspension – 10ml	02/10/98	Feb 2008 – June 2015	Treatment of acute otitis externa in adult and pediatric patients, one year or older, due to susceptible strains of <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> , and <i>Proteus mirabilis</i> .	4 drops into affected ear twice a day for 7 days.