

STEP THERAPY POLICY

- POLICY:** Otic Quinolone – Ciprofloxacin Step Therapy Policy
- Cetraxal® (ciprofloxacin 0.2% otic solution – WraSer)
 - Ciprodex® (ciprofloxacin 0.3%/dexamethasone 0.1% otic suspension – Novartis, generic)
 - Cipro® HC OTIC (ciprofloxacin 0.2%/hydrocortisone 1% otic suspension – Alcon)
 - Ciprofloxacin 0.2% otic solution (generic only)
 - Ciprofloxacin 0.3%/fluocinolone acetonide 0.25% otic solution – Xspire (branded product)
 - Otovel® (ciprofloxacin 0.3%/fluocinolone acetonide 0.025% otic solution – Arbor)

REVIEW DATE: 10/4/2023

OVERVIEW

All of these products are indicated for the treatment of patients with ear infection.

- **Acute otitis externa** due to susceptible isolates of *Pseudomonas aeruginosa* and *Staphylococcus aureus*: Cetraxal, Ciprodex, generic ciprofloxacin 0.2% otic solution, Cipro HC OTIC.¹⁻⁴ Cipro HC OTIC is also active against acute otitis externa due to *Proteus mirabilis*.⁴
- **Acute otitis media with tympanostomy tubes** due to *S. aureus*, *Haemophilus influenzae*, *Moraxella catarrhalis*, and *P. aeruginosa*: Ciprodex, Otovel, ciprofloxacin 0.3%/fluocinolone acetonide 0.025% otic solution.^{2,5,8}

Cetraxal is a brand-only single-entity product containing ciprofloxacin 0.2%; ciprofloxacin 0.2% otic solution is also available as a generic product.^{1,3} Ciprodex, Cipro HC OTIC, ciprofloxacin 0.3%/fluocinolone acetonide 0.025% otic solution, and Otovel are combination products containing a corticosteroid.^{2,4,5,8}

Ciprofloxacin otic solution, Cetraxal, ciprofloxacin 0.3%/fluocinolone acetonide 0.025% otic solution, and Otovel are preservative-free products.^{1,3,5,8} Ciprodex is preserved with benzalkonium chloride and Cipro HC OTIC is preserved with benzyl alcohol.^{2,4}

Guidelines

The American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) published their clinical practice guidelines for acute otitis externa in patients ≥ 2 years of age (2014).⁶ The guidelines recommend the use of an ototopical antibiotic for initial therapy of diffuse acute otitis externa because of excellent clinical and bacteriologic outcomes, low incidence of adverse events (AE), likelihood of adherence to therapy, and cost. The guidelines do not prefer one agent over another.

The AAO-HNSF guidelines for the management of children with tympanostomy tubes (2022) recommend the use of ototopical antibiotics, without oral antibiotics, in children with uncomplicated acute tympanostomy tube otorrhea.⁷ The guidelines do not prefer one ototopical product over another. The advantages of ototopical products in acute otitis media with tympanostomy tubes include increased drug concentration at the site of infection, improved coverage of likely pathogens, and no systemic AEs.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: generic ciprofloxacin otic solution, generic ciprofloxacin-dexamethasone otic solution

Step 2: Cetraxal, Ciprodex, Cipro HC OTIC, ciprofloxacin 0.3%/fluocinolone acetonide 0.025% otic solution (branded product), Otovel

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. No other exceptions are recommended.

REFERENCES

1. Cetraxal[®] otic solution [prescribing information]. Ridgeland, MS: WraSer; December 2017.
2. Ciprodex[®] otic suspension [prescribing information]. East Hanover, NJ: Novartis; November 2020.
3. Ciprofloxacin otic solution [prescribing information]. Madison, MS: Xspire Pharma; August 2012.
4. Cipro[®] HC Otic suspension [prescribing information]. East Hanover, New Jersey; August 2020.
5. Otovel[®] otic solution [prescribing information]. Atlanta, GA: Arbor; April 2016.
6. Rosenfeld RM, Schwartz SR, Cannon CR, et al. Clinical practice guideline: Acute otitis externa. *Otolaryngol Head Neck Surg.* 2014;150:S1-S24.
7. Rosenfeld RM, Tunkel DE, Schwartz SR, et al. Clinical Practice Guideline: Tympanostomy tubes in children (Update). *Otolaryngol Head Neck Surg.* 2022;166(1 Suppl):S1-55.
8. Ciprofloxacin/fluocinolone acetonide otic solution [prescribing information]. Ridgeland, MS: Xspire; June 2021.