

# SmartPA Criteria Proposal

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|-----------------------------------|--|
| <b>Drug/Drug Class:</b>           | Fluoroquinolones, Otic PDL Edit  |
| <b>First Implementation Date:</b> | May 17, 2006   |
| <b>Proposed Date:</b>             | March 18, 2021   |
| <b>Prepared For:</b>              | MO HealthNet   |
| <b>Prepared By:</b>               | MO HealthNet/Conduent  |
| <b>Criteria Status:</b>           | <input type="checkbox"/> Existing Criteria<br><input checked="" type="checkbox"/> Revision of Existing Criteria<br><input type="checkbox"/> New Criteria |

## Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** The fluoroquinolones are synthetic, broad-spectrum antibacterial agents that inhibit DNA gyrase. DNA gyrase is an essential enzyme that is involved in the replication, transcription, and repair of bacterial DNA. All of the fluoroquinolones are effective in treating both gram-positive and gram-negative infections, however, there is considerable fear regarding the virulence of gram-negative organisms such as pseudomonas. The clinical evidence suggests that all the products within this therapeutic class are efficacious for the vast majority of otic infections including acute otitis externa, acute otitis media in patients with tympanostomy tubes and chronic suppurative otitis media.

Total program savings for the PDL classes will be regularly reviewed.

| Program-Specific Information: | Preferred Agents  | Non-Preferred Agents   |
|-------------------------------|---|--|
|                               | <ul style="list-style-type: none"> <li>Ciprodex®</li> </ul> | <ul style="list-style-type: none"> <li>Cipro HC®</li> <li>Ciprofloxacin Otic</li> <li><b>Ciprofloxacin/Dexamethasone</b></li> <li>Ciprofloxacin/Fluocinolone</li> <li>Ofloxacin Otic</li> <li>Otiprio™</li> <li>Otovel®</li> </ul> |

**Type of Criteria:**  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Clinical Edit

**Data Sources:**  Only Administrative Databases  Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Fluoroquinolones, Otic
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 1 preferred agent
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents

## Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

## Required Documentation

Laboratory Results:   
MedWatch Form:

Progress Notes:   
Other:

## Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)  
Rule Type: PDL

## Default Approval Period

1 year

## References

1. Evidence-Based Medicine Analysis: "Otic Quinolones – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; March 2021.
2. Evidence-Based Medicine Analysis: "Otic Fluoroquinolones", UMKC-DIC; January 2021.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2021.
4. USPDI, Micromedex; 2021.
5. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.