

SmartPA Criteria Proposal

Drug/Drug Class:	Fluoroquinolones, Otic PDL Edit
First Implementation Date:	May 17, 2006
Proposed Date:	April 18, 2023
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <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"> Ciprodex® 	<ul style="list-style-type: none"> Cipro HC® Ciprofloxacin Otic Ciprofloxacin/Dexamethasone Ciprofloxacin/Fluocinolone Ofloxacin Otic Otovel®

Type of Criteria: ☐ Increased risk of ADE
☐ Appropriate Indications

☒ Preferred Drug List
☐ 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 in the past 3 months
 - 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

- Evidence-Based Medicine and Fiscal Analysis: "Therapeutic Class Review: OTIC PREPARATIONS: Fluoroquinolone & Combination Agents", Gainwell Technologies; Last updated February 9, 2023.
- Evidence-Based Medicine Analysis: "Otic Fluoroquinolones", UMKC-DIC; Last updated January 2023.
- USPDI, Micromedex; 2023.
- Facts and Comparisons eAnswers (online); 2023 Clinical Drug Information, LLC.